SetPoint System Prescriber Instructions for Use

Read all instructions, warnings and cautions carefully. Failure to follow them could lead to damage to the SetPoint System, cause it to malfunction, degrade its performance and/or result in harm.

Contact SetPoint Medical with any questions about the information contained in the **SetPoint System Patient Instructions for Use** (Patient IFU). Copies of all SetPoint System Instructions for Use (IFUs) are available on the SetPoint Medical website. Any SetPoint System-related incident or problem, which is believed to represent a safety issue, should be reported to SetPoint Medical, Inc. immediately.

CONTACT INFORMATION:

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Valencia, CA 91355-5004
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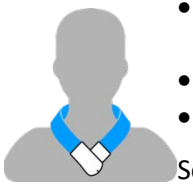
Email: support@setpointmedical.com
www.setpointmedical.com

Caution: Federal law restricts this device to sale by or on the order of a physician.

Prescriber Quick Reference Guide

It is important to read and understand the entire contents of this Prescriber IFU prior to use of the SetPoint System. It is also important to provide the patient with the Patient IFU and to train them on how to use their SetPoint System using section **Patient Quick Reference Guide**. Once training is complete, ask the patient to demonstrate their understanding and provide further training on areas that need reinforcement. Make sure to brief the patient on contraindications and warnings using section **Important Safety Information.**

Charger Fit Confirmation



- Prior to the implant procedure, either place the Charger, or instruct the patient to place the Charger around their neck while they are seated upright.
- Verify that the magnetic latch closes and remains latched without discomfort.
- Remove the Charger or instruct the patient to remove the Charger.

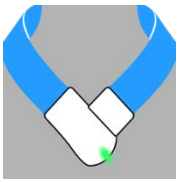
See section **Charger Fit Confirmation** for more details.

Unpacking and Issuing the Charger

- Unpack the Charger and Docking station and plug the Docking Station into power.
- Place the Charger briefly on the Docking Station to wake up the Charger. No charging is required.
- Train the patient on how to use their SetPoint System and provide them with the Patient IFU QR code.

See sections **Unpacking and Issuing the Charger** and **Patient Quick Reference Guide** for more details.

Connecting Programmer, Charger, and Implant



- Place and close the Charger around the patient's neck.
- Confirm the connection with Implant; indicated by **two beeps that go *up* in tone** and **green** or **orange** LED on the Charger.

- Launch and log in to Programmer.
- Press "Select" under the patient's Charger in Programmer.
- Tap twice on the Charger's magnetic latch to authorize connection; confirmation is indicated by **one single long beep**.
- Confirm the Implant serial number matches the patient's record.

See section **Connecting Programmer to Charger and Implant** for more details.

The information contained herein is not a substitute for a complete and thorough understanding of all the instructions presented in the Prescriber IFU. Please refer to the relevant sections in the Prescriber IFU for all pertinent information concerning use of the SetPoint System, and safety and efficacy information.

Prescription Management

Creating a Prescription

- Connect Programmer, Charger, and Implant.
- Press “Create Prescription” in the Prescription Panel.

See section **Creating the Prescription** for more details.

Editing a Prescription

- Press “Edit” to right of “Strength.”
- Adjust the prescription in 50-250 µA increments to determine a comfortable stimulation strength.
- Test the dose for 15 seconds by pressing “Test Dose Strength.”
- If the test dose is uncomfortable, let discomfort resolve, then decrease the dose strength by 50 µA and retest. Repeat until stimulation is comfortable.
- Accept or reject the dose by pressing “Accept” or “Reject.”
- Save prescription by pressing “Accept” and “Save.”

See section **Adjusting Dose Strength** for more details.

Suspending Therapy

- Press the Implant Panel.
- Press “Suspend Therapy” and then “Suspend.”
- Ensure the Charger LED shows **solid pink**.

See section **Suspending Therapy** for more details.

Resuming Therapy

- Press the Implant Panel or Prescription Panel.
- Press “Resume Therapy.”
- When prompted, press “Resume” to confirm.
- Ensure the Charger LED shows **green** or **orange**.

See section **Resuming Therapy** for more details.

The information contained herein is not a substitute for a complete and thorough understanding of all the instructions presented in the Prescriber IFU. Please refer to the relevant sections in the Prescriber IFU for all pertinent information concerning use of the SetPoint System, and safety and efficacy information.

Patient Quick Reference Guide

This page is a summary that explains the important points about using the SetPoint System. In addition, you should also watch the training video by clicking this link or scanning this QR Code with your mobile device:

SetPoint System Use & Care

Charging

- Keep your Charger on your Docking Station when you are not wearing it to keep it charged.
- You will know your Charger is fully charged when its LED is **solid green**, or when your Docking Station's LED is **solid blue**.
- Make sure your Charger is fully charged when you bring it to the clinic.

Cleaning

- Use a dry, lint-free cloth to clean your Charger, avoiding the magnetic latch.
- If needed, use isopropyl alcohol (IPA) wipes to clean lotion and oils off your Charger and to clean the magnetic latch area.
- Never spray your Charger with any substance or put it in any liquid.
- Keep lint and dirt out of your Charger's magnetic latch area.

Implant Charging

- Wear your Charger around your neck and make sure the magnetic latch closes properly.
- Charging begins when your Charger's LED **blinks green**, or **orange** and you hear **three beeps that go *up* in tone**.
- You will know charging is done when your Charger's LED is **solid green,** and you hear **four beeps (three beeps that go *up* in tone and a fourth beep that is a repeat of the last tone)**.
- It is recommended that you establish a routine to charge your Implant on the same day and time every week.

Travel

- Always carry your Charger in its Carrying Case when taking it somewhere.
- Do not use your Charger while traveling in cars, trains, boats, planes, or other vehicles.
- Provide your Patient ID card to security personnel when going through airport security if they have any questions or concerns about your SetPoint System.

Do not go into places with signs that warn about radio frequency (RF) safety.	Contact the clinic right away if you start to feel any pain or discomfort.	Charge your Implant weekly.

The information contained herein is not a substitute for a complete and thorough understanding of all the instructions presented in the Patient IFU. Please refer to the relevant sections in the Patient IFU for all pertinent information concerning use of the SetPoint System, and safety and efficacy information.

Table of Contents

Introduction

This **SetPoint System Prescriber Instructions for Use** (Prescriber IFU) describes the operation and intended use of the SetPoint System and the process for programming the SetPoint System. The SetPoint System is to be used only by healthcare professionals who have reviewed and understand this Prescriber IFU.

The table below shows the SetPoint System model numbers for the parts of the system that are described in this IFU.

Device Name	Model Number
Implant	M01
Charger	E04
Docking Station	C01

Table 1 - Device Names and Model Numbers

Indication for Use

The SetPoint System is indicated for the treatment of adult patients with moderately to severely active RA who have had an inadequate response, loss of response or intolerance to one (1) or more biological or targeted synthetic DMARDs.

Pediatric Use

The SetPoint System is not intended for use in the pediatric population.

SetPoint System Description

The SetPoint System includes:

- The Implant (A) which is placed within a Pod (B) and implanted on the left vagus nerve in the neck (C)
- A Charger (D) with Docking Station (F)
- A Programmer (E)

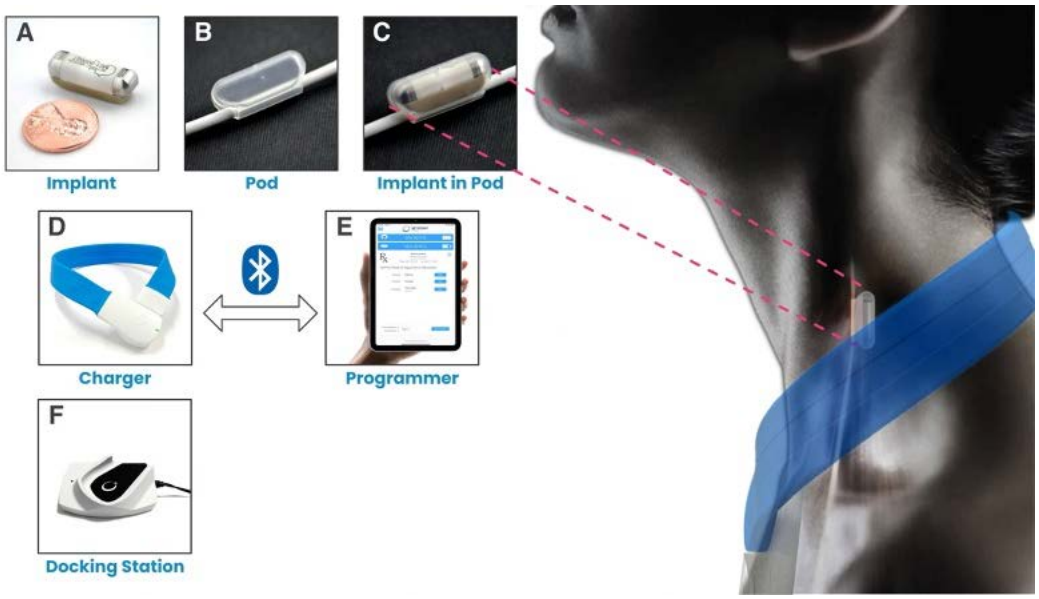


Figure 1 - SetPoint System and Components

Implant and Pod

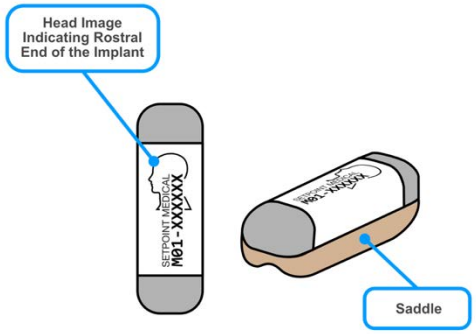


Figure 2 - Implant

The Implant is an integrated neurostimulation device. It is used to electrically stimulate the vagus nerve for 1 minute, every day. It is about 1 in (2.5 cm) long and weighs about 0.1 oz (3 g). An experienced surgeon implants it next to the vagus nerve on the left side of the neck. The Implant is placed inside a Pod, which is a flexible cover made of silicone. The Pod helps hold the Implant in place.

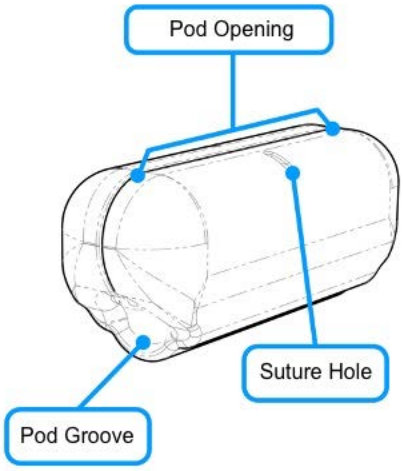


Figure 3 - Pod

For more information regarding the use of the Implant or Pod, please refer to the **SetPoint System Surgeon Instructions for Use** available on the SetPoint Medical website.

Charger

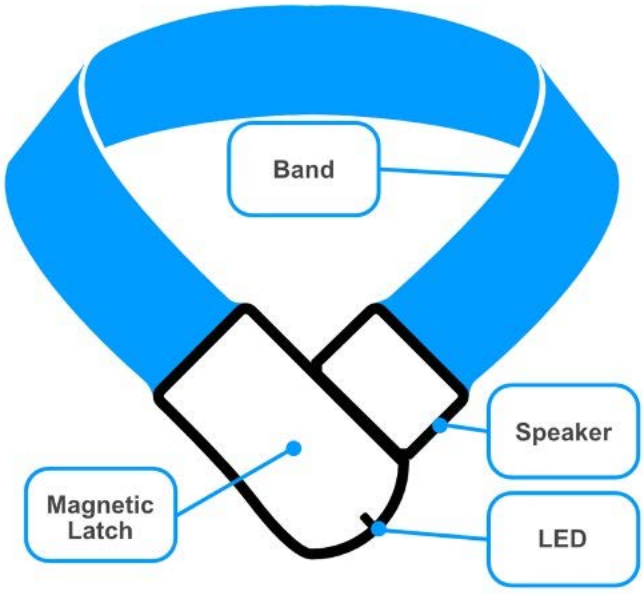


Figure 4 – The Charger

The Charger is a device worn around the patient's neck. It is used for charging the Implant at home and for programming the Implant at the clinic. It is recommended to be worn once a week to charge the Implant.

The Charger is about 24 in (61 cm) long and 1.5 in (3.8 cm) wide, when unlatched and laid flat, and weighs about 9 oz (270 g). The Charger does not have any buttons or switches, but it does have an LED and a speaker.

The Charger only comes in one size that is meant to fit most people, forming a circular ring about 21 in (53 cm) in circumference when latched. Before the implant procedure, it is necessary to perform a fit and tolerability test on the patient. This makes sure it fits comfortably around their neck and that the magnetic latch closes.

Docking Station

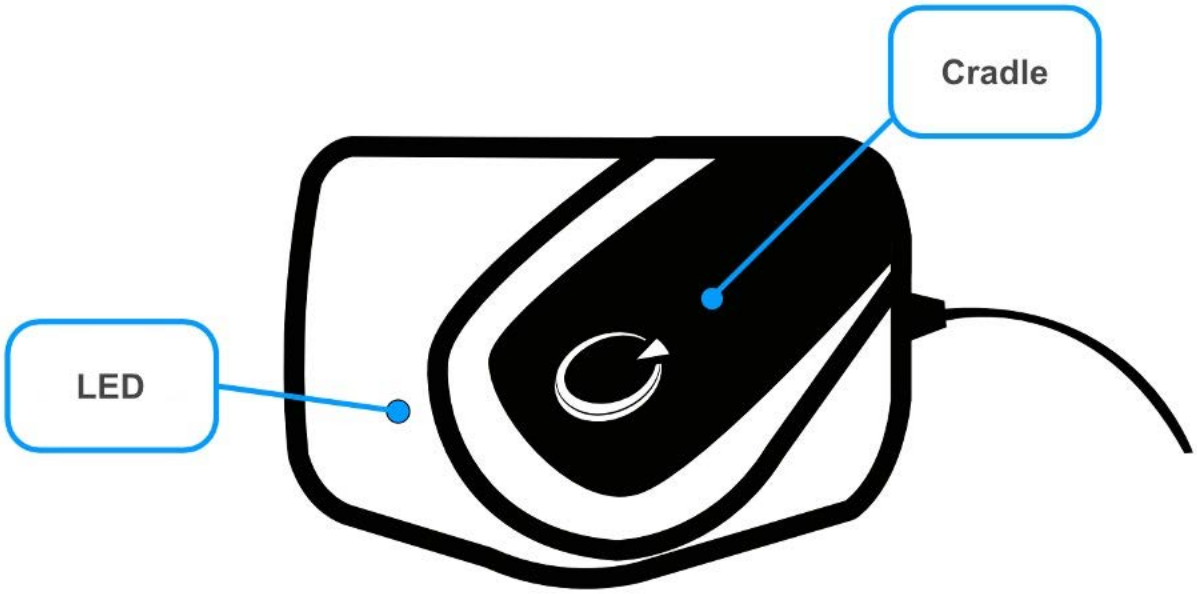


Figure 5 – The Docking Station

The Docking Station is provided with the Charger. The Docking Station is for charging and storing the Charger. Only the Docking Station provided in the Carrying Case should be used to charge the Charger. Use of any other wireless power supply may damage the Charger, the wireless power supply, or both.

The Docking Station is about 4.5 in (11.4 cm) wide, 3 in (7.6 cm) deep, and 2 in (5.0 cm) tall, and weighs about 10 oz (290 g). The Docking Station does not have any buttons or switches, but it does have an LED. The Docking Station has a cradle for placing the Charger on and a power cord that must be plugged into an electrical outlet. The Docking Station cannot be serviced at home or in the clinic. The Docking Station is meant to be used indoors and should always stay plugged in.

Carrying Case

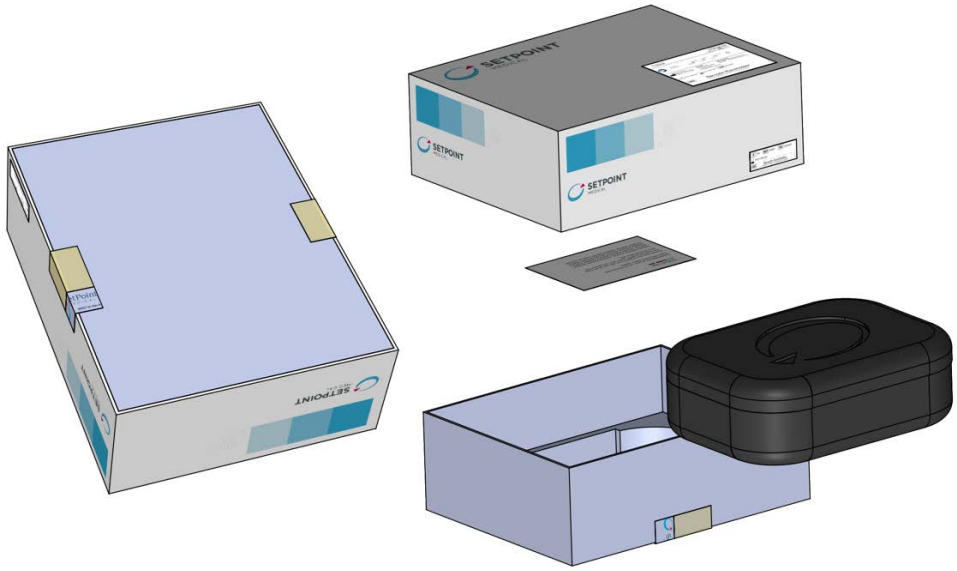


Figure 6 – Carrying Case Inside Sealed Product Box

The Charger and Docking Station are provided in a Carrying Case shipped inside of a product box. The product box is sealed with tamper evident labels. See **Unpacking and Issuing** the Charger for instructions on how to unpack the Charger.

Programmer

Programmer is an app installed on an Apple iPad® that is only used by a trained healthcare professional. It is used with the Charger to program the Implant or to turn off or resume stimulation, if necessary. Additionally, it gives the healthcare professional information about the use of the Implant and Charger, such as how many doses have been delivered or missed, and Implant battery charge levels.

Patient Identification (ID) Card

The Patient ID Card, shown in Figure 7, is included in the Implant packaging. The Patient ID Card is filled out and provided to the patient after the surgery, and before they leave the hospital. Patients should be instructed to always have their Patient ID Card on hand and present it during security screenings, such as at airports. Additionally, the QR code on the card provides access to critical information regarding the Implant, which is necessary to ensure that any treatments are compatible with it. Instruct the patient to always present the Patient ID card to healthcare professionals, dentists, or estheticians before pursuing any additional medical, medical imaging or beauty treatments. Neglecting to inform these professionals about the Implant may cause harm to the SetPoint System and/or may lead to complications with the treatment. If the patient changes doctors, or loses their card, they should contact SetPoint Medical for a replacement card.

Figure 7 - Sample Patient ID Card (Front and Back)

Important Safety Information

Read all instructions, warnings and cautions carefully. If you have any questions, contact SetPoint Medical. If the patient does not follow these guidelines, the SetPoint System could get damaged, not work correctly, and/or result in harm.

Contraindications

There are certain situations in which the SetPoint System should not be used because the risk(s) are greater than the potential benefit(s).

The SetPoint System should not be used:

- If the patient has had certain health procedures that would interfere with how the device works, for example,
  - If they have had surgery to remove the vagus nerve (vagotomy).
  - If they have had their spleen removed (splenectomy).
- If you determine that it might not be safe for them to have the surgery, for example,
  - If they have spine disease in their neck that makes it risky to place a breathing tube (intubate).
  - If they cannot be safely given anesthesia for surgery.
- If they cannot safely use SetPoint Charger, for example,
  - If their neck is too large to wear SetPoint Charger.
  - If they have a pacemaker or a defibrillator implanted.

Warnings & Precautions

It is important that the patient use the SetPoint System safely to avoid injury or damage to the SetPoint System or other devices. Here are some key safety tips:

- Instruct the patient to always present the Patient ID card to healthcare professionals, dentists, or estheticians before pursuing any additional medical, medical imaging or beauty treatments. If they do not, the treatment may cause harm to the SetPoint System and/or may lead to complications with the procedure.
- Instruct the patient not to scuba dive or enter a hyperbaric chamber after receiving the Implant. The safety of high pressure has not been established and these conditions could damage the device.
- Instruct the patient not to use the SetPoint Charger while it is covered (e.g., with a scarf or similar material), in direct sunlight, or in air temperatures exceeding 90 °F (32 °C). If they do, it may cause the Charger to overheat rapidly and shut down prematurely.
- Instruct the patient not to continue to use the SetPoint Charger or Docking Station beyond their expected service life (5 years for the Charger, 10 years for the Implant). If they do, it can lead to additional risks associated with deterioration of the device over time. Signs of performance degradation include incomplete Implant charging during the weekly session.
- Do not use the SetPoint Charger or Docking Station if any cracks, defects, or breaches are present, or if the product box or Carrying Case are badly damaged. If you do, damaged internal electrical components could alter the Charging or Docking Station function or bypass safety features and result in harm.
- Instruct the patient not to use third-party wireless chargers with the SetPoint Charger or try to charge other devices with the SetPoint Docking Station. Using incompatible accessories with the SetPoint System could lead to device damage or malfunction.
- Instruct the patient not to position the SetPoint Charger around the neck if there are any unhealed wounds. If they do, it increases the risk of infection.

- Instruct the patient not to apply excessive force or rough handling to the SetPoint Charger. If they do, it may damage its internal electrical components, potentially causing malfunction.
- Instruct the patient not to use any cleaning product other than isopropyl alcohol (IPA) wipes to clean the SetPoint Charger. If they do, it could damage the Charger or leave behind harmful or irritating residues.
- Instruct the patient to adhere to local e-waste regulations when disposing of any part of the SetPoint System. If they do not, it can result in environmental contamination with hazardous substances.
- Instruct the patient not to modify or tamper with the SetPoint Charger or Docking Station. If they do, it could alter their function or bypass safety features and result in harm.

Medical Imaging Warnings

There are various types of medical imaging technologies in common use. Although X-rays, computed tomography (CT), ultrasound imaging (sonography), positron emission tomography (PET) are all safe to perform after the patient receives their Implant, it is vital that they always show their Patient ID card to any healthcare professional performing these procedures. Specifically for magnetic resonance imaging (MRI), although they can have scans 2 weeks after implantation, they can only be performed under certain conditions as outlined in **SetPoint System Magnetic Resonance Imaging (MRI) Safety Information Manual**. This is referred to as MR Conditional and must be discussed with the MRI technician.

Figure 8 - MR Conditional

The SetPoint Charger and SetPoint Docking Station should never be brought near MRI machines because they are not safe for use in that environment. This is referred to as MR Unsafe.

Figure 9 - MR Unsafe

Medical Procedure Warnings

Instruct the patient to use caution with any medical procedure that introduces electrical current, electromagnetic radiation, or thermal energy into tissues in the neck area. The Implant may absorb, intensify, or reflect these energy sources, resulting in localized heating that could damage the device or nearby nerves and vascular structures. This damage may result in pain or discomfort, loss of vocal cord function, or even possibly life-threatening injury if there is damage to blood vessels. Note that these risks are present whether the Implant is active or suspended. It is vital that they always show their Patient ID card to any healthcare professional performing these procedures so that they can carefully evaluate potential interactions and risks. Before proceeding with any procedure that delivers energy to the tissues surrounding the Implant, the healthcare professional should consider alternatives that avoid energy transfer. Specific examples of higher risk procedures around the implantation site that need to be avoided because they could damage the Implant, cause it to malfunction, and/or result in harm including severe injury:

- Shortwave diathermy, microwave diathermy, ultrasound diathermy or other procedures that induce heat in internal tissues. This does not include diagnostic ultrasound which is permitted.
- Electrosurgery/electrocautery, and ablation techniques that utilize any form of electromagnetic radiation or electrical current to cut, coagulate, or thermally destroy tissues. For electrocautery, do not use within 2 cm

of the Implant. If using monopolar electrocautery, place the return pad such that the current path is not across the Implant.

- Transcutaneous electrical nerve stimulation (TENS), electroconvulsive therapy or other procedures that apply electrical current through skin surface electrodes.
- Extracorporeal shock wave lithotripsy or other procedures that use pressure waves or induce mechanical forces to break up internal structures.
- Radiation therapy, including forms of photon beam radiation therapy such as x-rays, gamma rays, proton beam therapy, brachytherapy, stereotactic radiosurgery, cobalt machines, and linear accelerators.

Radio Frequency (RF) Warnings

The SetPoint System uses radio frequency (RF) fields for communication between different parts of the system or when charging the Implant or Charger. These RF fields could disrupt the functioning of similar frequency-utilizing devices. Instruct the patient not to use the Charger for charging the Implant near devices sensitive to RF interference, while travelling in vehicles such as cars, trains, boats, airplanes, or during any medical treatments, or in proximity to other medical devices. The SetPoint System has not been tested with, and may affect the operation of, other implanted devices, such as cardiac pacemakers and implanted defibrillators. Possible effects include, but are not limited to, sensing problems and inappropriate device responses. The RF signals from the Charger could theoretically interfere with or be concentrated by other implanted devices such as neural stimulators or insulin pumps.

The Charger and Docking Station are vulnerable to electromagnetic interference from devices that emit RF fields, like cellphones and security scanners. Portable RF communications equipment (including peripherals such as antenna cables and external antennas), RFID scanners and card readers (including animal identification tag scanners) should be used no closer than 12 inches (30 cm) to any part of the Charger and Docking Station. Otherwise, degradation of the performance of this equipment could result. If it is suspected that the Charger or Docking Station are not functioning correctly due to electromagnetic interference, try changing the patient's location, waiting until a later time, or turning off the suspected source of interference if possible. Use of the Charger or Docking Station adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the Charger and Docking Station should be observed to verify they are operating normally.

The Charger and Docking Station are intended for use indoors, for example in the home or clinic. They should not be used in environments where the intensity of electromagnetic disturbances is known to be high, such as near high-frequency surgical equipment or radio transmitters. They should also not be used in any environment with a posted FCC Notice, Caution or Warning sign indicating the presence of high-intensity radio frequency (RF) fields that surpass normal public exposure limits. These areas are typically indicated by restricted environment signs like those in Figure 10. After receiving the implant, the patient should not enter these areas without seeking medical guidance first. Exposure to high levels of RF could cause the Implant to malfunction or lead to tissue damage in the vicinity of the device.

Figure 10 - Restricted Environment Signage

Other Help Using the SetPoint System

In addition to the information provided in this Prescriber IFU, supplementary training materials including, but not limited to, a training presentation and programming videos are available and can be provided upon request. Additional training, if requested, can be arranged with your local SetPoint Medical representative.

Using the SetPoint System

The table below shows the conditions for transport, storage, and use of the Charger and Docking Station.

Use	Temperature	Humidity	Altitude
Transport: In Carrying Case	50 to 104 °F (10 to 40 °C)	15 to 93 %RH	Up to 98,425 ft (30,000 m)
Storage: Charger on Docking Station			Up to 9,843 ft (3,000 m)
Use: Charging the Implant	50 to 90 °F (10 to 32 °C)		

Table 2 – Transport, Storage, and Use Conditions

⚠ **Warning:** Instruct the patient not to scuba dive or enter a hyperbaric chamber after receiving the Implant. The safety of high pressure has not been established and these conditions could damage the device.

⚠ **Warning:** Instruct the patient not to use the SetPoint Charger while it is covered (e.g., with a scarf or similar material), in direct sunlight, or in air temperatures exceeding 90 °F (32 °C). If they do, it may cause the Charger to overheat rapidly and shut down prematurely.

The Charger normally heats up during use, potentially reaching up to 118 °F (48 °C). To prevent overheating and premature shutdown, the Charger needs to be at or below 90 °F (32 °C) before being used to charge the Implant. If the Charger has been stored above 90 °F (32 °C), it must be allowed to cool down to this temperature, which can take up to 10 minutes.

⚠ **Warning:** Instruct the patient not to continue to use the SetPoint Charger or Docking Station beyond their expected service life (5 years for the Charger and 10 years for the Implant). If they do, it can lead to additional risks associated with deterioration of the device over time. Signs of performance degradation include incomplete Implant charging during the weekly session.

The rechargeable battery in the Charger is rated to last for at least 5 years. If the patient cannot complete the weekly Implant charging session with a fully charged Charger, the entire Charger may need to be replaced as its battery cannot be replaced or serviced at home. Contact SetPoint Medical if you believe there are any issues with the Charger.

The rechargeable battery in the Implant is rated to last for at least 10 years. The Implant may need to be replaced if it can no longer deliver daily stimulation as the Implant's battery cannot be replaced. You will be able to determine this by looking at information provided by the Programmer during a clinic visit. Contact SetPoint Medical if you believe there are any issues with the Implant.

Charger Fit Confirmation

To confirm fit of the Charger prior to the implantation procedure, the following steps shall be performed:

1. Prior to the implant procedure, either place the Charger, or instruct the patient to place the Charger around their neck while they are seated upright.
2. Verify that the magnetic latch closes and remains latched without discomfort.
3. Remove the Charger or instruct the patient to remove the Charger.

Automatic Prescription Dosing

The Implant is programmed with an automatic prescription, relying on the Implant's built-in timer to maintain the dosing schedule. When the Implant is delivering stimulation to the vagus nerve, the patient may or may not

feel a sensation near the location of the Implant. Instruct the patient to contact the clinic if the stimulation becomes uncomfortable, and the clinic personnel should adjust the prescription based on their comfort level.

Unpacking and Issuing the Charger

The Charger and the Docking Station will be issued to the patient in a Carrying Case (see Figure 11-3). The Charger is shipped in a deactivated state to preserve the battery life and must be placed on the Docking Station to take it out of shipping mode prior to the first use. This Carrying Case should be used whenever the patient is transporting the Charger. At home, the patient should unpack the Charger and Docking Station, plug the Docking Station into an electrical outlet, and place the Charger on the Docking Station.

⚠ **Warning:** Do not use the SetPoint Charger or Docking Station if any cracks, defects, or breaches are present, or if the product box or Carrying Case are badly damaged. If you do, damaged internal electrical components could alter the Charging or Docking Station function or bypass safety features and result in harm.

Figure 11 - Unpacking Charger and Docking Station

1. Cut the tape to open the product box.
2. Remove the Carrying Case and Patient IFU QR code from the product box and provide the QR code to the patient.
3. Place the Carrying Case on a flat surface with the logo on top and the handle facing away from you.
4. Unzip the Carrying Case and flip the top open.
5. Remove the Charger from the Carrying Case and set it aside.
6. Remove the Docking Station from the Carrying Case.
7. Uncoil the power cord and plug the Docking Station into an electrical outlet.
8. Place the Docking Station on flat surface, with enough room to accommodate the Charger once placed on the Docking Station and where you can ensure that the Docking Station is at least 8 in (20 cm) away from you during use.
9. Confirm that the Docking Station has a **solid pink** LED before placing the Charger on the Docking Station. If the LED is not showing a **solid pink** light, see **Appendix D – Troubleshooting**.

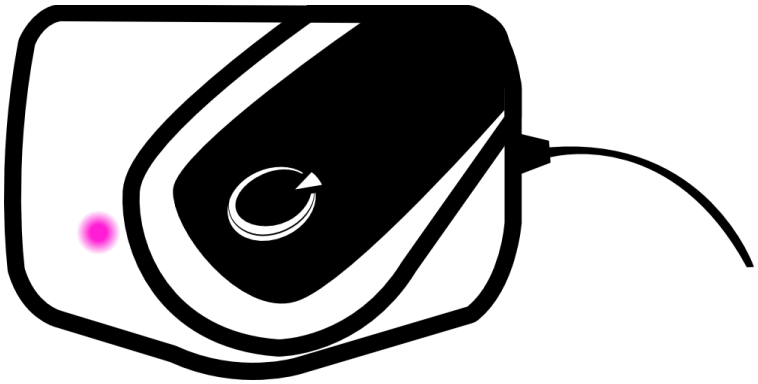


Figure 12 - The Docking Station shows a solid pink LED when it is plugged in, but not charging the Charger.

10. After confirming the Docking Station has a **solid pink** LED it is ready to use. It is best to leave the Docking Station in a location where it does not need to be moved.
11. Place the Charger briefly on the Docking Station to take it out of shipping mode. No charging is required.

Charging the Charger

⚠ **Warning:** Instruct the patient not to use third-party wireless chargers with the SetPoint Charger or try to charge other devices with the SetPoint Docking Station. Using incompatible accessories with the SetPoint System could lead to device damage or malfunction.

The Charger should be placed on the Docking Station whenever it is not being transported or used to charge the Implant (whenever it is not being worn).

1. Place the Charger on the Docking Station's cradle as shown, ensuring the Charger is latched closed. The Charger must be latched while charging.

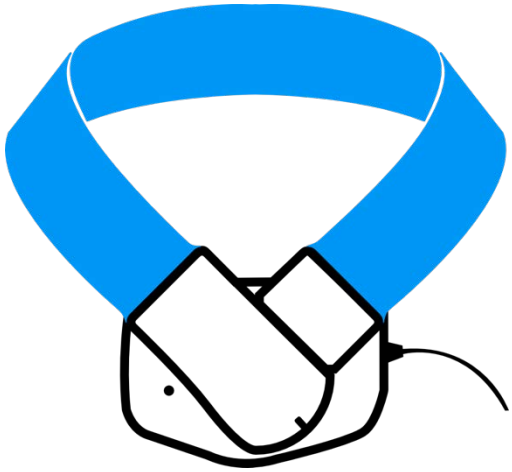


Figure 13 - The Charger must be latched closed when placed on the Docking Station's cradle.

2. The Docking Station's LED will begin **blinking blue** to show that it is charging. If the Charger is fully charged, the Docking Station's LED will display **solid blue**. If the Docking Station does not show a **blinking** or **solid blue** LED, see **Appendix D – Troubleshooting**.

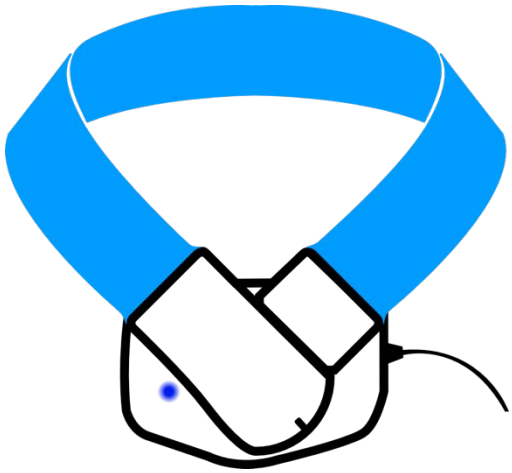


*Figure 14 - The Docking Station's LED **blinks blue** when charging the Charger or shows **solid blue** when charging is complete.*

3. While the Charger is placed on the Docking Station's cradle, tapping on the Charger logo will show its state of charge. If the Charger LED shows **solid green**, it is done charging. If the Charger LED shows **blinking green**, it has enough charge to charge the Implant. If the Charger LED shows **blinking orange**, it is charging but not ready yet to charge the Implant.

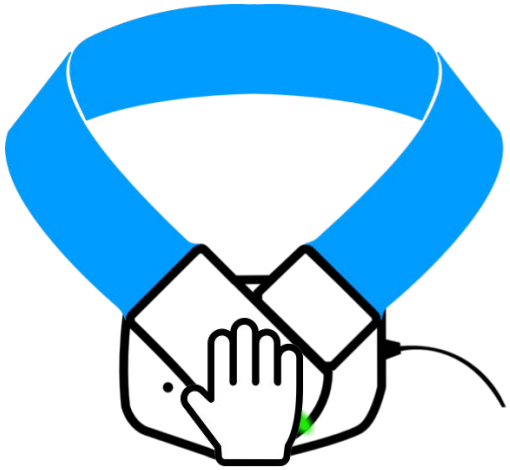


Figure 15 - Tapping on the Charger while it is on the Docking Station will show its state of charge.

Even if the Charger is done charging, there is no need to take it off the Docking Station. Leaving the Charger on the Docking Station ensures that it is always fully charged.

Before the patient visits the clinic or charges their Implant, they should make their Charger has a full charge by tapping on the Charger logo while it is on the Docking Station and looking for a **solid green** LED.

Charging the Implant

SetPoint Medical recommends charging the Implant each week using the Charger.

⚠ **Warning:** Do not position the SetPoint Charger around the neck if there are any unhealed wounds. If you do, it increases the risk of infection.

The Charger is only to be placed on skin without cuts or wounds. If the Charger needs to be used on an open wound, the wound should be covered in sterile gauze or bandage first.

For ease of use, the Charger has both an LED and a speaker for showing charge status. If needed, patients can use a mirror to look at the Charger LED.

1. Tap on the Charger logo while it is on the Docking Station and look for a **green** LED. If the LED is **orange**, leave the Charger on the Docking Station until it turns **green**.
2. Remove the Charger from the Docking Station.
3. Unlatch the Charger by pulling or twisting the two halves of the magnetic latch apart. Do not touch the pins on the inside of the magnetic latch.
4. Carefully lift the Charger over the patient's head or bring it around their neck. The magnetic latch should rest on the front of the patient's neck with the SetPoint logo half on their right side.
5. Take both halves of the magnetic latch and press them together. The magnets in the Charger should snap into place and latch easily. If the Charger is hard to latch, it is likely twisted or upside down.
6. Make sure the latch is securely closed so the Charger will not fall off. Adjust it so it sits comfortably on the patient's neck.

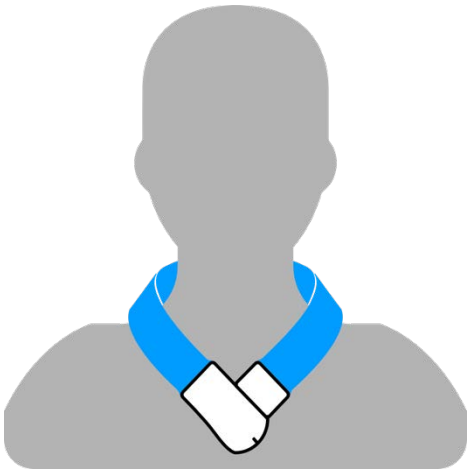


Figure 16 - The Charger should rest comfortably around the neck as shown.

7. The Charger's LED will begin to **slowly pulse white** while it is trying to connect to the Implant. Once it has connected to the Implant, the Charger will play **two beeps that go *up* in tone**. If at any time after connection it plays **two beeps that go *down* in tone**, it means the Charger has lost connection with the Implant.
8. The Charger will play **three beeps that go *up* in tone** when it begins charging the Implant and will then display an **orange** or **green** LED.
9. It is recommended that the Implant be charged for approximately 5 minutes per week or until the battery is full, whichever comes first. The Charger's LED shows **solid green** and plays **four beeps (three beeps that go *up* in tone and a fourth beep that is a repeat of the last tone)** when the Implant battery is full. After the Implant has reached full charge, the beeps will repeat every 30 seconds until you take the Charger off.
10. Once charging is completed, unlatch the Charger and remove it from the patient's neck.
11. Latch the Charger and place it back on the Docking Station.

Following a Routine

Creating a routine can make it easier to remember when to charge the Charger and Implant. SetPoint Medical recommends the following routines:

1. The patient should wear the Charger to charge their Implant for about 5 minutes on the same day each week. For example, they may choose to charge the Implant every Sunday morning or right before going to bed every Saturday night. Less frequent charging may require longer time to fully charge the Implant
2. When not wearing the Charger, it should be placed on the Docking Station. This makes sure that the Charger always has a full charge when it is needed for charging the Implant or for a clinic visit.

Traveling With and Packing the Charger and Docking Station

⚠ **Warning:** Do not apply excessive force or rough handling to the SetPoint Charger. If you do, it may damage its internal electrical components, potentially causing malfunction.

When at home, it is important to follow the recommended routine outlined above to maintain the devices' batteries. When traveling, the patient should consult you on what equipment they should take with them depending on the length of their trip. If they need to bring the Charger or Docking Station, they should always use the Carrying Case.

The patient should bring their Charger to the rheumatologist visit as it may be needed to adjust the programming on their Implant. If they are planning a long trip that requires the Docking Station, they should bring a standard plug adapter if traveling internationally.

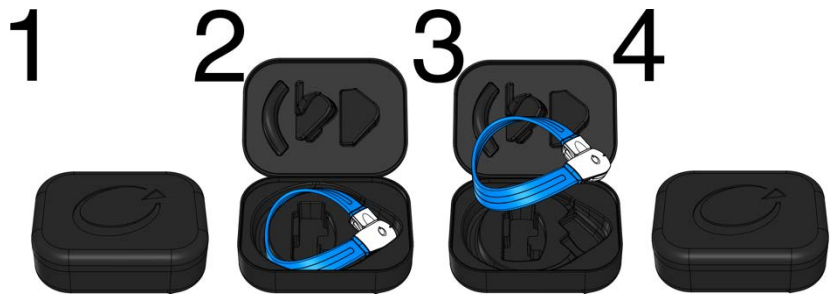


Figure 17 – Packing the Charger in the Carrying Case

1. Place the Carrying Case on a flat surface with the logo on top and the handle facing away.
2. Unzip the Carrying Case and flip the top open.
3. Place the latched Charger in the Carrying Case.
4. Zip the Carrying Case shut.

The Charger cannot be turned off, but it switches to low power mode by itself after about 1 minute of inactivity. Opening or closing the Charger or removing the Charger from the Docking Station will wake it up, and it will begin looking for an Implant.

The patient should pack the Carrying Case in their carry-on luggage when traveling in an airplane. They should provide their Patient ID card to security personnel when going through airport security if they have any questions or concerns about the SetPoint System. See https://www.tsa.gov for more information about traveling with medical equipment.

Cleaning

⚠ **Warning:** Instruct the patient not to use any cleaning product other than isopropyl alcohol (IPA) wipes to clean the SetPoint Charger. If they do, it could damage the Charger or leave behind harmful or irritating residues.

- Use a dry, lint-free cloth to clean the Charger avoiding the magnetic latch.
- If needed, use isopropyl alcohol (IPA) wipes to clean lotion and oils off the Charger and to clean the magnetic latch area.
- Never spray the Charger with any substance or put it in any liquid.
- Keep lint and dirt out of the Charger's magnetic latch area.

Replacement and Disposal

⚠ **Warning:** Instruct the patient to adhere to local e-waste regulations when disposing of any part of the SetPoint System. If they do not, it can result in environmental contamination with hazardous substances.

To reorder the Charger or Docking Station, contact SetPoint Medical and request Catalog Number 90007. The Docking Station is not sold separately from the Charger. Please dispose of the Charger and Docking Station per local E-Waste regulations.

Setting Up to Use Programmer

Programmer is an iPad application that is used to program and interrogate the SetPoint System. An internet connection is required (see section **Troubleshooting Network Connectivity** for details) for installation and use of Programmer. All patient data is stored securely in the cloud, so Programmer on any iPad can be used for programming and interrogating any Implant using any Charger. For storage and handling of the iPad, refer to the iPad Owner's Manual, or check Apple support at https://support.apple.com.

Understanding Programmer's User Interface

The main components of the interface are the following (see Figure 18):

1. **Menu Icon**: used to modify a logged-in user's account, view clinic's prescription history, view application information, and log out of application
2. **Charger Panel**: used to select and initiate connection to a Charger; view Charger information, serial number, firmware versions, and battery state of the Charger
3. **Implant Panel**: used to view Implant information, serial number, firmware version, battery state of the Implant, and impedance status; suspend and resume therapy
4. **Prescription Panel**: used to create, modify, and print prescriptions; view adherence data

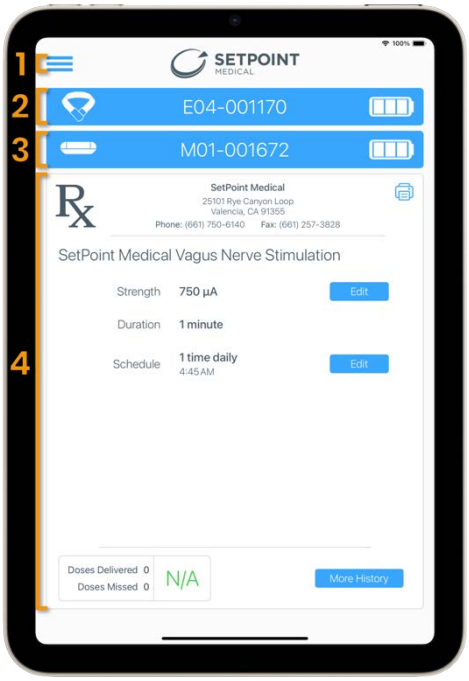


Figure 18 - Locating Programmer's Application Panels

Downloading Programmer

Programmer can be installed on any iPad capable of running the latest version of iPadOS. If the iPad already has Programmer installed, the following download steps should be skipped.

1. Navigate to Apple's App Store from your iPad and search for "SetPoint Programmer".
2. Select "Get" in the App Store.
3. Follow the instructions on the iPad to install the application.

Creating an Account

Before healthcare professionals can connect to the SetPoint System with Programmer, they will need to create a SetPoint Medical account and have that account approved by SetPoint Medical. Each healthcare professional should have their own, unique SetPoint account. A SetPoint account may be created using an email address and password or by signing in with an existing login provider (e.g., Microsoft or Apple).

1. Press the application icon to launch Programmer.

Figure 19 - Programmer Application Icon

2. Press “Create SetPoint Account”.

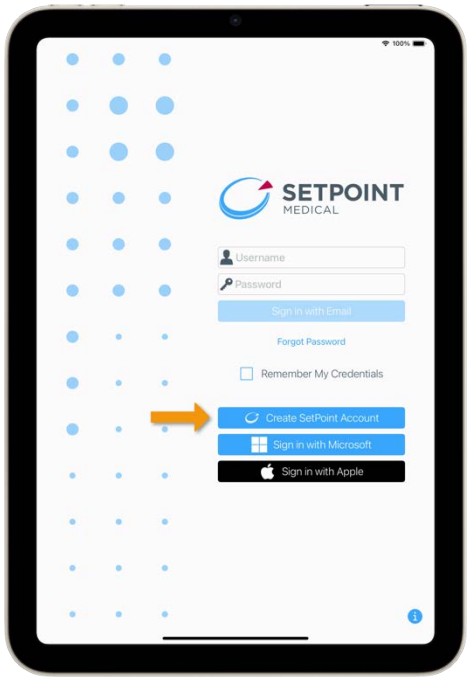


Figure 20 - Create SetPoint Account

3. To use your own email and password, enter the email you wish to have associated with your SetPoint Medical account and press “Continue”. Then enter a new password and press “Continue”.

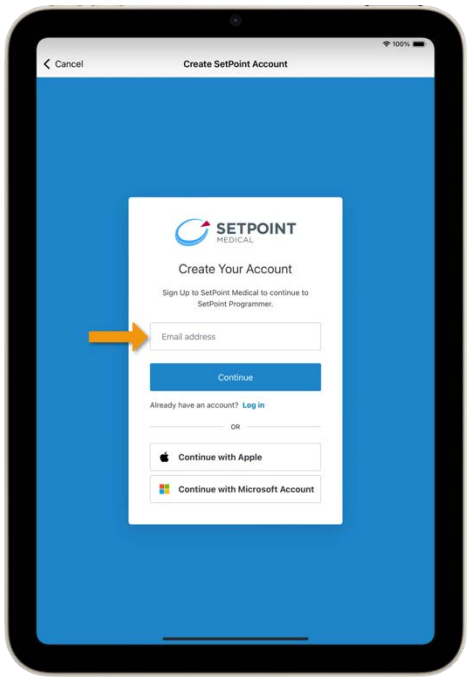


Figure 21 – Create an Account with Email

4. Alternatively, to use an account and password managed by an alternate login provider, select the login provider from the list of available options and follow the on-screen instructions from that provider.

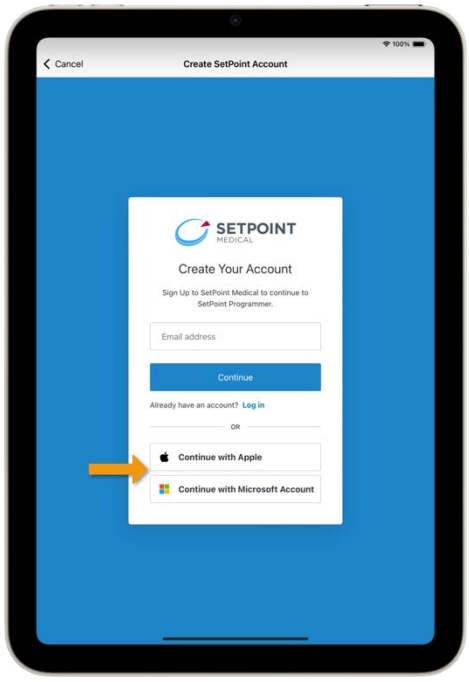


Figure 22 - Create an Account with an Alternate Login Provider

5. Once your account has been created, you will be prompted to verify your email. An email will be sent to the email address provided during account creation, and it must be verified before you may log in.

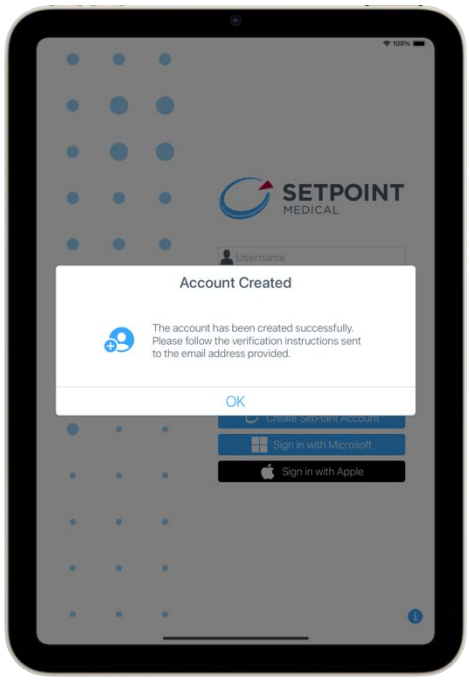


Figure 23 - Prompt Indicating Successful Account Creation

6. In the email titled “Verify Your SetPoint Medical Account”, select “Verify My Account”.

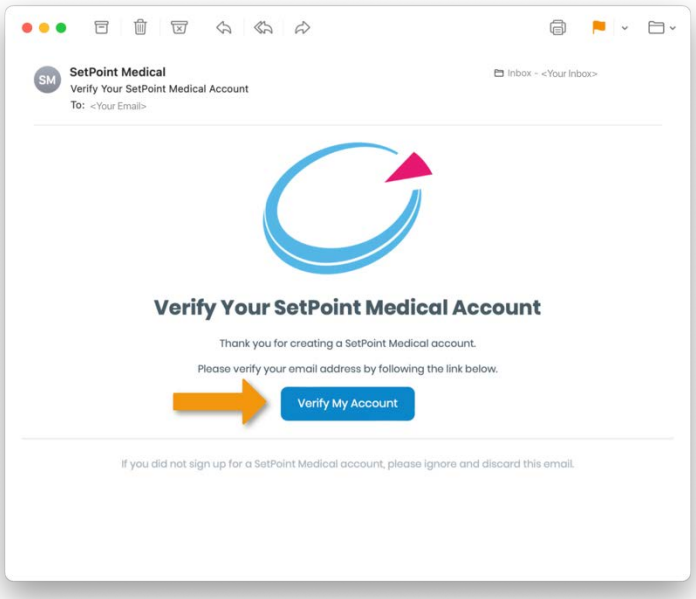


Figure 24 – The “Verify My Account” Button in the Account Verification Email

7. Once your email has been verified, you may now log in to your account. However, you will not be able to connect to SetPoint Medical devices until your account has been approved for use after verification that you are a healthcare professional. Either your SetPoint representative or an existing user at your clinic with an activated account must make a request by sending an email to

programmers@setpointmedical.com. You will receive a confirmation email at the specified address when your account is activated.

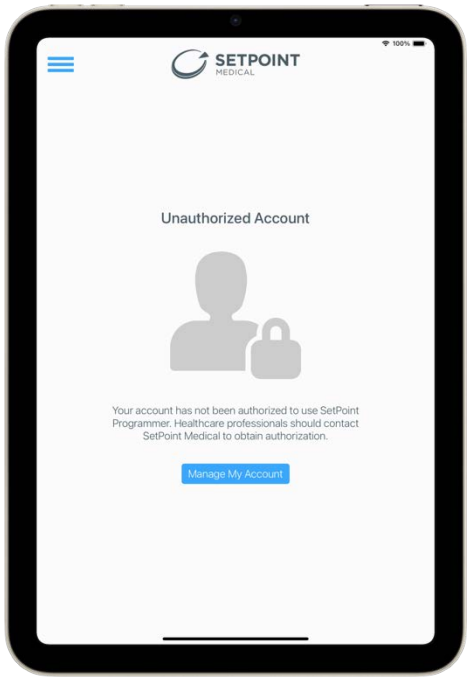


Figure 25 - Accounts have limited access to Programmer until confirmed as healthcare professionals.

Logging In and Controlling Your Account

Logging In

1. To log in with email and password credentials, enter your username and password in the fields provided and press “Sign in with Email”. Checking “Remember My Credentials” will allow you to use Apple’s Face ID®, Touch ID®, or a connected Apple Watch® to expedite future sign-ins.

Figure 26 - Login with Email and Password Credentials

2. If your account was created with an alternate login provider, select the provider from the list below and follow the on-screen prompts to perform login.

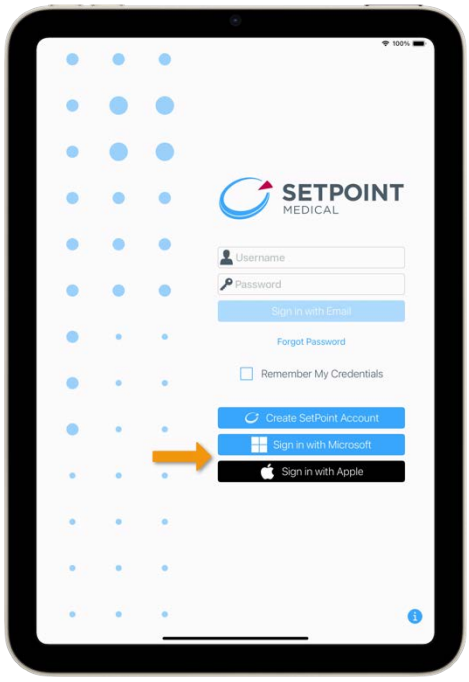


Figure 27 - Login with an Alternate Identity Provider

3. If your account is protected with multi-factor authentication, you may be presented with a prompt asking to select your second authentication factor.

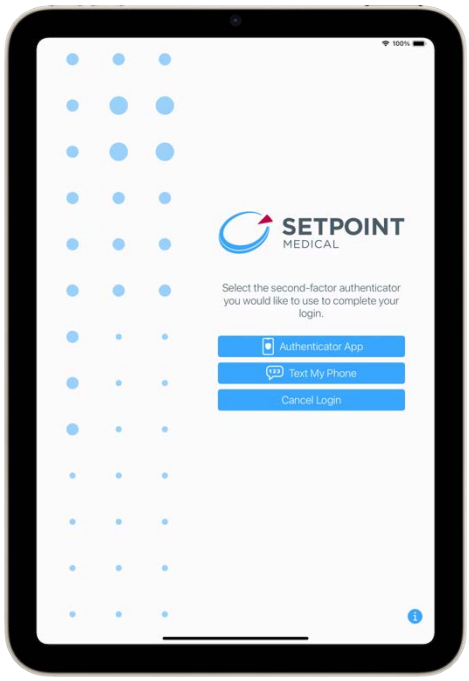


Figure 28 - Select a second authentication factor.

4. If entering a second authentication factor, enter the one-time passcode provided and press “Verify Code”.

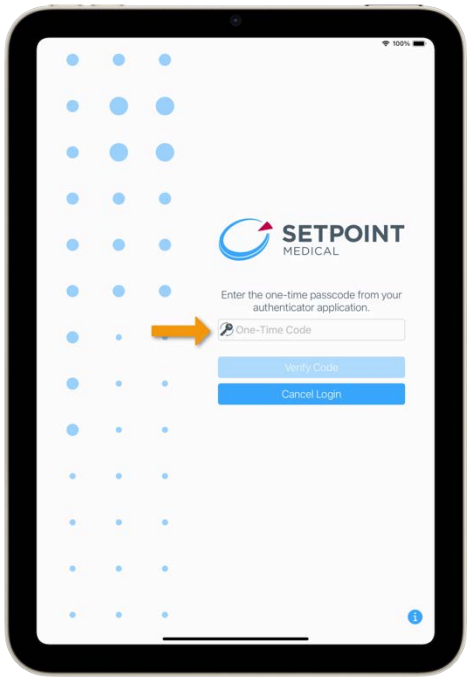


Figure 29 - Entering a One-Time Passcode for the Second Factor

5. If logging in for the first time, an End-User License Agreement will appear. Review the license and press “Agree” to agree to the terms of the license.

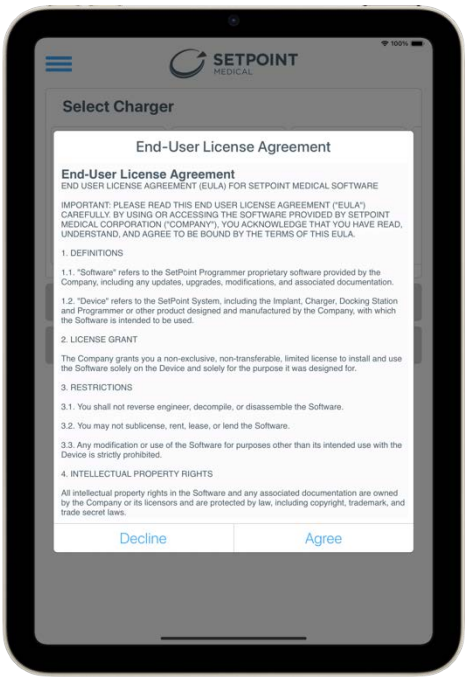


Figure 30 - End-User License Agreement

Updating User Details

Once logged in, you can modify your user details, including your name and an avatar. Press the menu icon in the upper left of the Programmer and then press “My Account”.

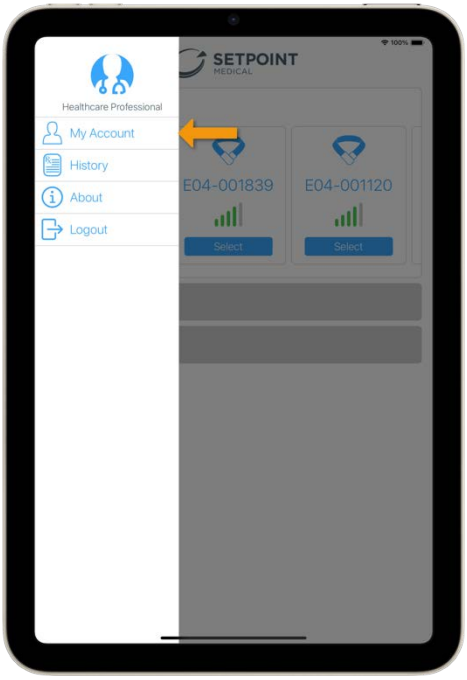


Figure 31 - Accessing the Account Manager

- To update your name in the SetPoint System, type in the Name field and press “OK”.

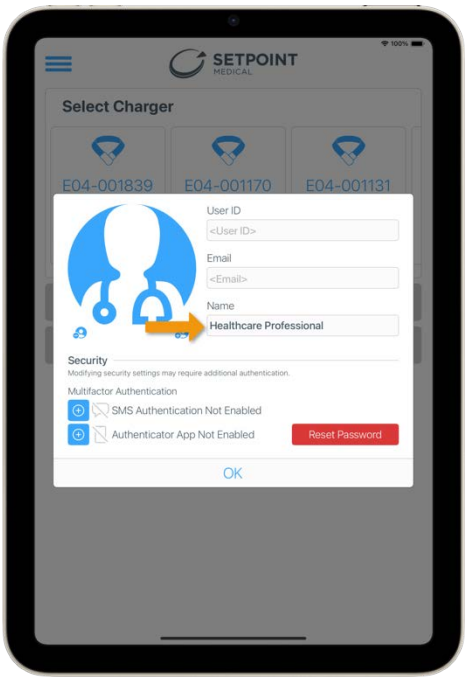


Figure 32 - Modifying Your Name

- To add an avatar image, press the “Add Avatar” button as shown below. Select a photo from the iPadOS’ built-in photo picker.

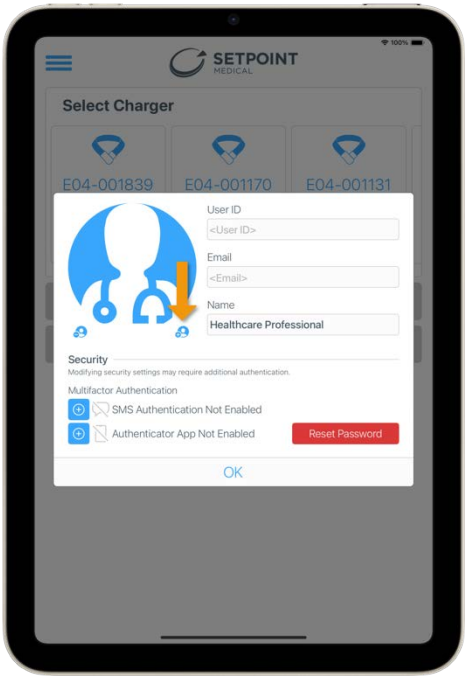


Figure 33 - Adding an Avatar

- To remove an avatar image, press the Remove Avatar button as shown below.

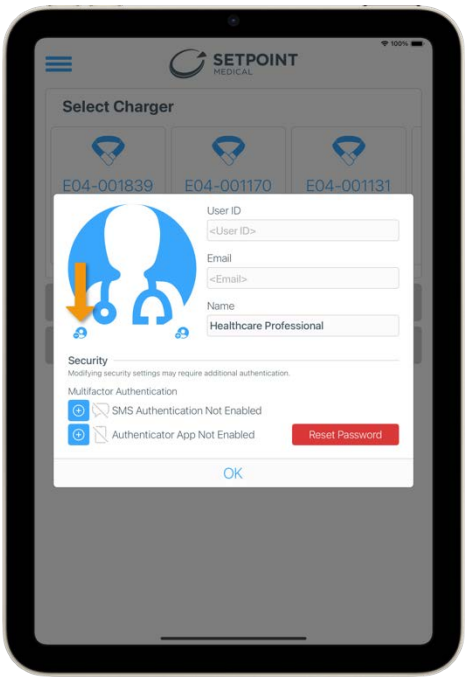


Figure 34 - Removing an Avatar

Resetting Password

Your password can be reset provided you have access to the email account with which you registered your account because SetPoint Medical does not have access to your password.

1. From the Login Screen, press “Forgot Password”.

Figure 35 - Press "Forgot Password" to begin a password reset.

2. Enter the email address with which your user account was registered.

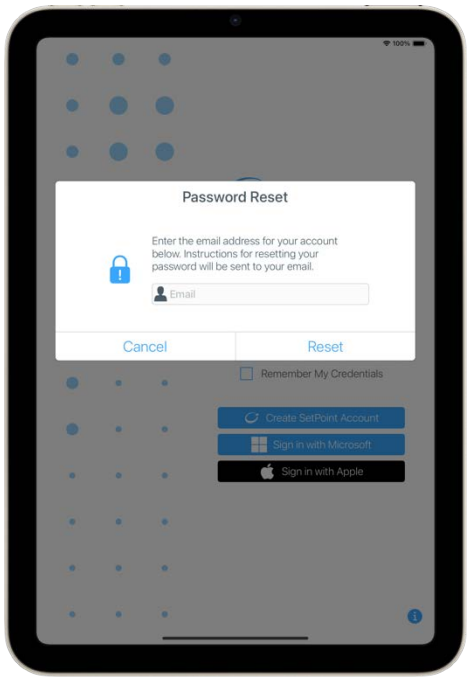


Figure 36 - Entering Your Account's Email Address for Password Reset

3. An email will be sent to the email address to reset the password. Open the email and select “Change My Password”.

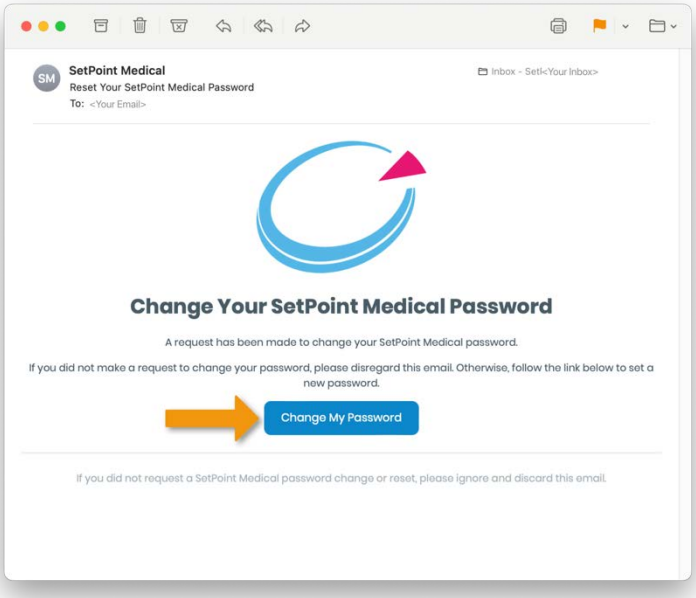


Figure 37 - The "Change My Password" Button in the Password Reset Email

4. Choose and confirm the new password.

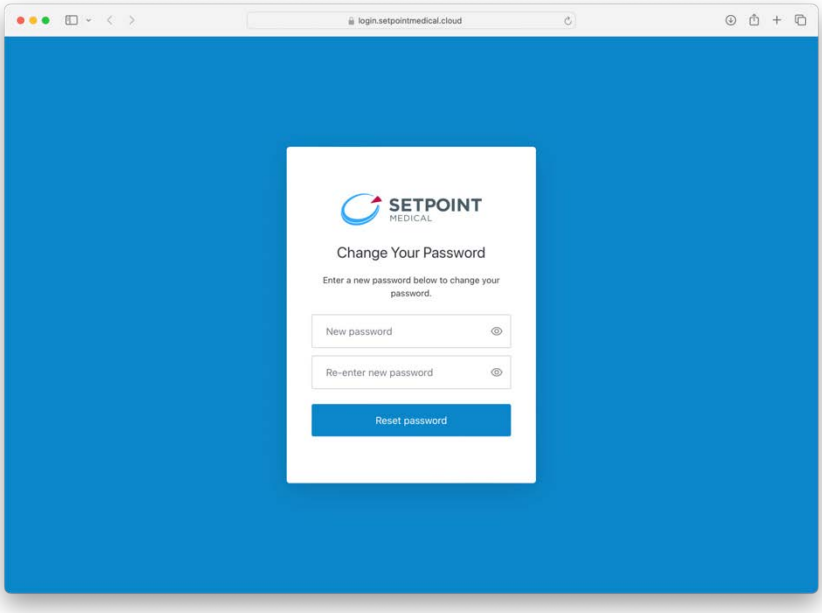


Figure 38 - Entering and Confirming Your New Password

5. A display will confirm the password was successfully changed.

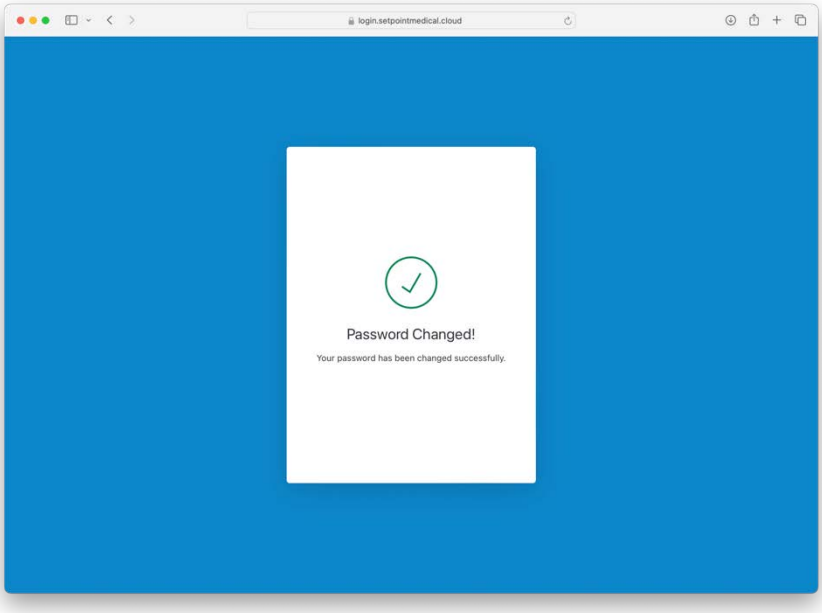


Figure 39 - Password Changed Confirmation

Managing Multi-Factor Authentication

SetPoint Medical does not require, but does recommend, that all healthcare professionals protect their account with multi-factor authentication. Programmer supports adding two forms of multi-factor authentication: having

one-time passcodes sent to your cellular phone via text message and using one-time passcodes from a third-party authenticator application (e.g., Microsoft Authenticator, Google Authenticator, Authy, etc.).

Adding a Text Message Authenticator

SetPoint Medical can send text messages with one-time passcodes as a secondary authentication factor. It should be noted that, to prevent spam attacks, only ten text messages may be sent per hour. Users that log into their accounts more frequently than ten times per hour may desire to use alternative authenticators.

1. After logging in to Programmer, navigate to the Account Manager as detailed in the section **Updating User Details**.
2. Press "+" next to the "SMS Authentication Not Enabled" text to turn on text message authentication.

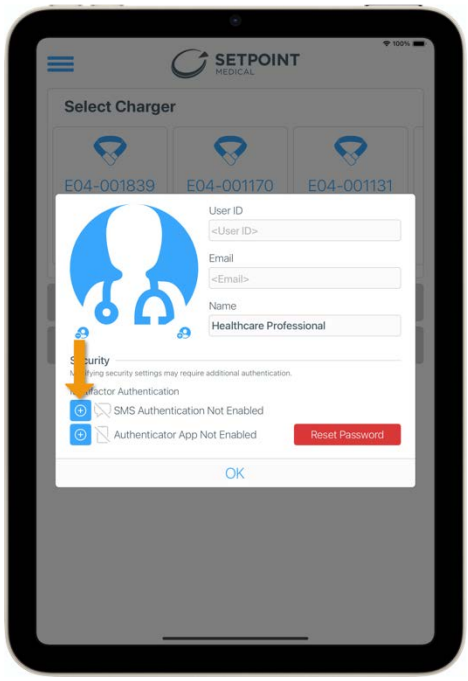


Figure 40 - Adding a Text Message Authenticator

3. Re-enter your credentials if prompted.
4. Enter the phone number to which you would like to receive one-time passcodes. The phone must be capable of receiving text messages. Standard text messaging rates from your carrier may apply.

Figure 41 - Phone Number Entry

5. An initial one-time passcode will be sent to the phone number provided. Enter the code and press “Continue” to confirm your phone number.

Figure 42 - Entering the One-Time Passcode to Confirm Your Phone Number

Adding an Authenticator Application

SetPoint Medical supports the use of third-party authenticator applications as a second authentication factor. Any authenticator application or password manager that supports the Time-based One Time Password (TOTP) authenticator format will work with the SetPoint System.

1. After logging in to Programmer, navigate to the Account Manager as detailed in the section **Updating User Details**.
2. Press the "+" button next to the "Authenticator Not Enabled" text.

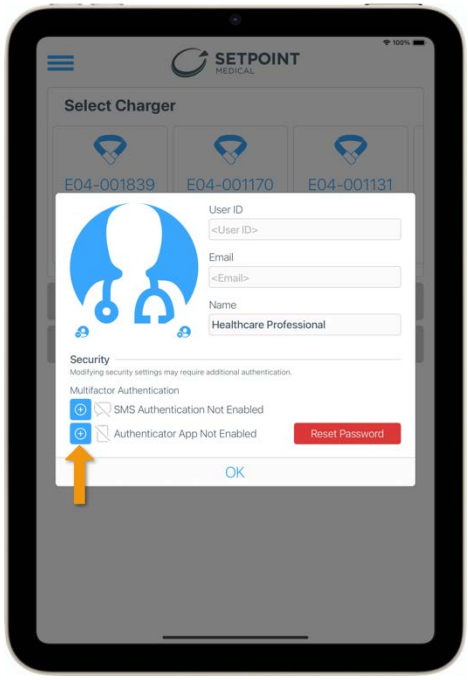


Figure 43 - Adding a Third-Party Authenticator App

3. Re-enter your credentials if prompted.
4. Using the third-party authenticator application of your choosing, scan the QR code provided and enter the one-time passcode the authenticator app provides.

Figure 44 - Confirming the Authenticator App (QR Code is Example Only)

Removing Authenticators

Once logged in, a user may remove their secondary authenticators.

1. After logging in to Programmer, navigate to the Account Manager as detailed in the section **Updating User Details**.
2. Press the button with the trash can icon next to the authenticator you wish to remove.

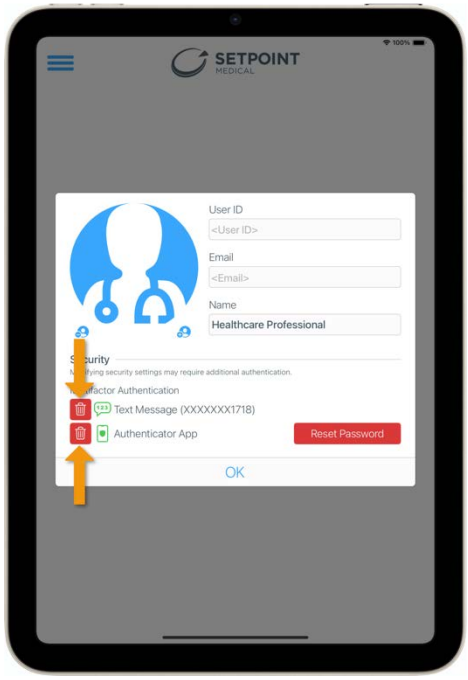


Figure 45 - Deleting Authenticators

3. Re-enter your credentials if prompted.

If you have lost access to all your secondary authenticators and can no longer access your account, you will need to contact SetPoint Medical to reset your account's multifactor authentication status. Additional steps may need to be performed to verify account ownership.

Programming the SetPoint System

Connecting Programmer to Charger and Implant

The patient's prescription is set by using Programmer in conjunction with the patient's Charger. Ensure the Charger is sufficiently charged prior to use by confirming a **green** LED. If the LED is **orange** the Charger is usable but should be charged soon. Refer to **Appendix A - Charger LED Status** and **Appendix B – Charger Speaker Status** for a full list of LED and speaker indications.

1. Place and close the Charger around the patient's neck.

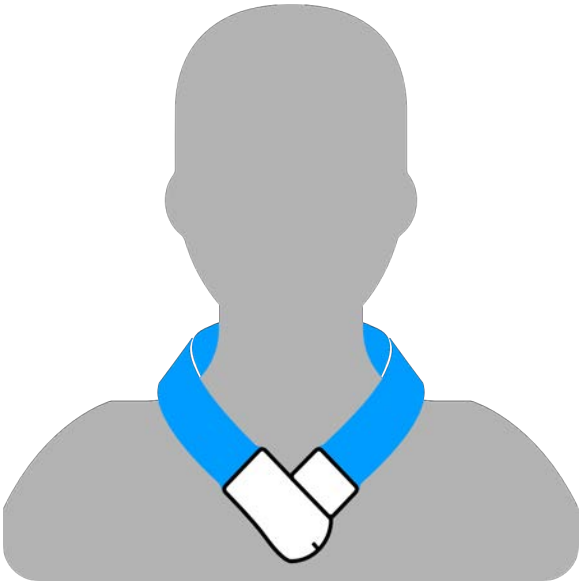


Figure 46 - A Properly Positioned Charger on a Patient

2. The Charger will automatically search for the Implant as indicated by a **pulsing white** LED.
3. Successful connection between the Charger and the Implant is indicated by **two beeps that go *up* in tone** and an **orange** or **green** LED depending on the state of the battery.
4. Launch and log in to Programmer.
5. If prompted to allow notifications, press "Allow".

Figure 47 - Allow notifications for important programming messages.

6. If prompted to allow Bluetooth connections, press “OK”.

Figure 48 - Bluetooth must be enabled to connect to devices.

7. Press “Select” below the serial number printed on the back of the patient’s Charger. If prompted with a “Bluetooth Pairing Request” message, press “Pair” to confirm.

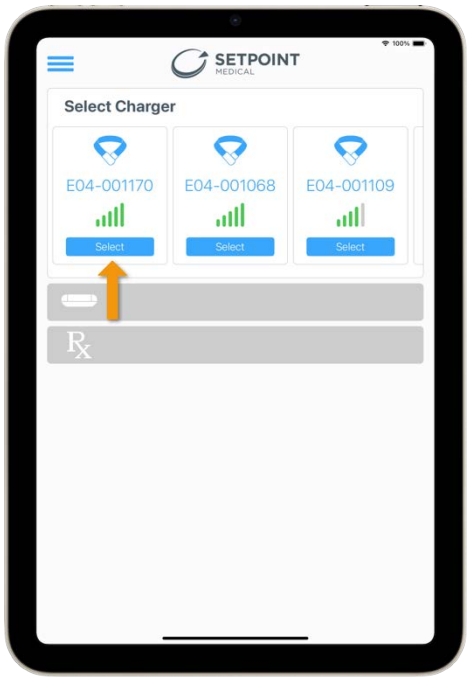


Figure 49 - The Programmer Charger Selection Screen

Figure 50 - Charger Bluetooth Pairing Request

8. Once the Charger LED begins **rapidly blinking blue**, tap twice on the Charger magnetic latch.

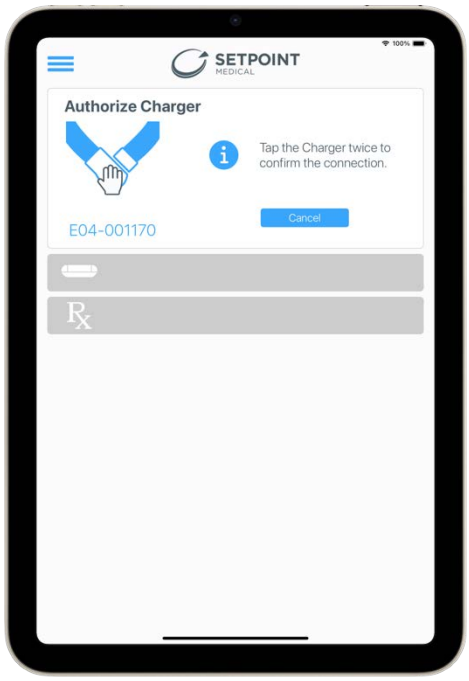


Figure 51 - Tap the Charger twice to confirm the connection to Programmer.

9. Successful connection of the Charger and Programmer is indicated by a **single long beep** on the Charger speaker and the Charger LED **periodically blinking blue**. If the Charger requires an update, it will show in the Charger Panel, press “Update” to start the process. After completion of an update, the connection to the Charger will need to be re-established.

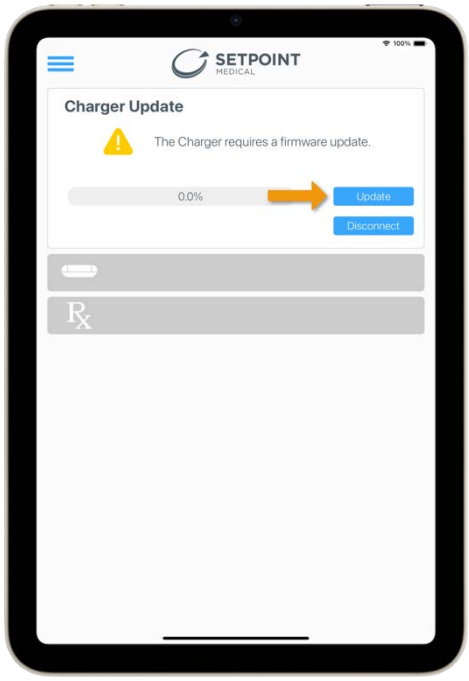


Figure 52 - Programmer will indicate if an update is required for the Charger.

10. If an update is not required, or after completion of the update, Programmer will indicate it is connecting to an Implant.

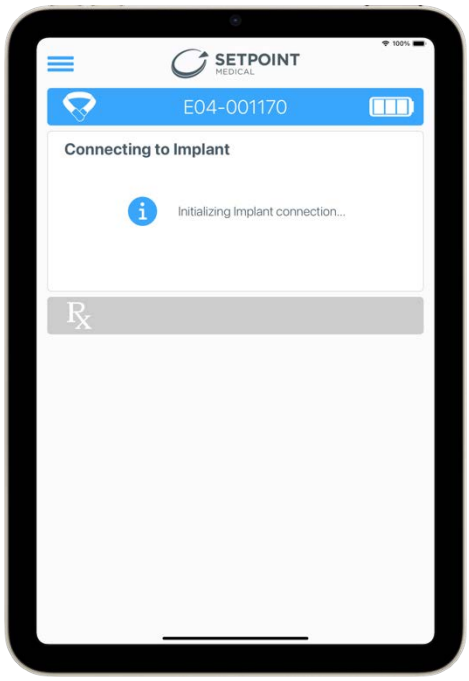


Figure 53 - Programmer will begin connecting to the Implant after connecting to the Charger.

11. Once Programmer is connected to the Implant, it will progress to the Implant Panel. If the Implant requires an update as shown in the Implant Panel, press “Update” to start the process.

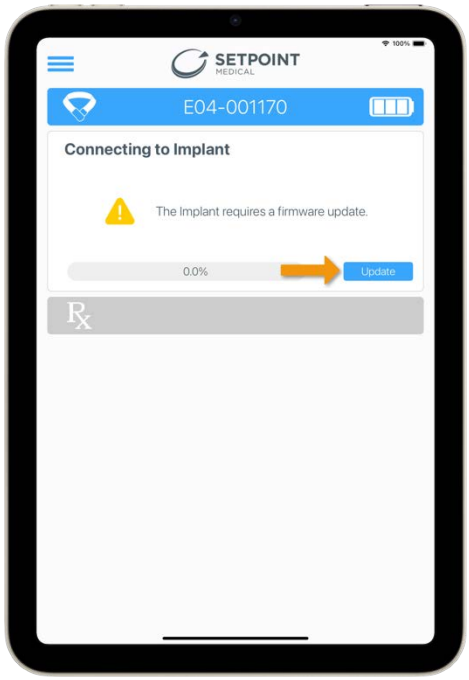


Figure 54 - Programmer will indicate if an update is required for the Implant.

12. The serial number of the connected Implant will be identified by Programmer. Confirm that the Implant serial number matches the serial number in the patient’s records or on the Patient ID card. If not, contact SetPoint Medical for troubleshooting.

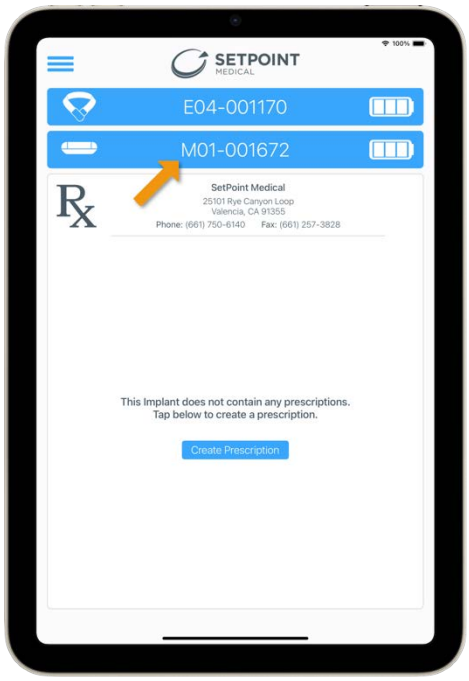


Figure 55 - The Implant serial number will be displayed in the Implant Panel of the Programmer.

13. If the Implant is not detected, the Charger LED will continue to **slowly pulse white,** and Programmer will alert you to confirm that the Charger is placed on the patient's neck and the latch is closed.

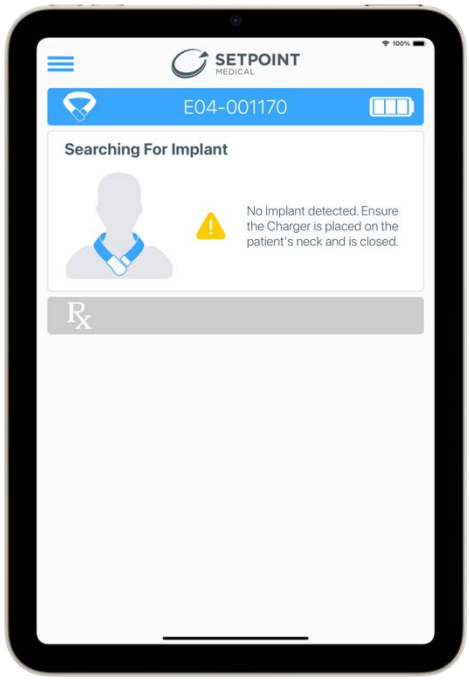


Figure 56 - If the Charger does not detect an Implant, confirm the Charger's placement on the patient and that it is latched closed.

14. If the Implant is still not detected even though the Charger is positioned properly on the patient's neck and the latch is closed, contact SetPoint Medical to troubleshoot.

Creating the Prescription

1. The first time the patient's Implant is programmed, it will not have a prescription. Press "Create Prescription".

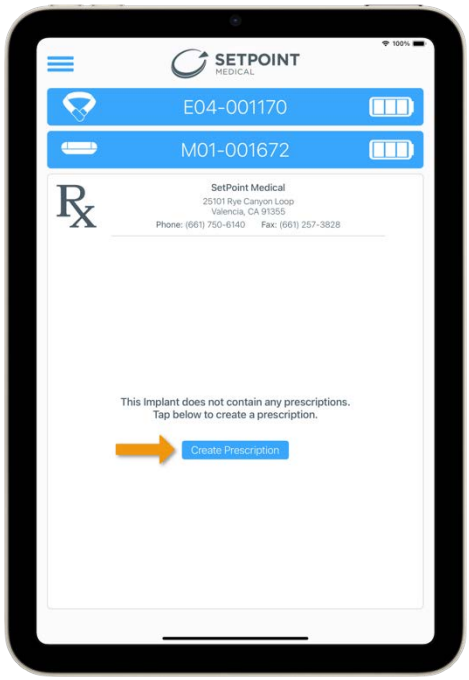


Figure 57 – Press "Create Prescription" to create the first prescription.

Adjusting Dose Strength

A default schedule for stimulation will be automatically set by Programmer when the first prescription is created. The dose duration and daily dose count will be automatically set by the Programmer and cannot be edited. Dose strength can be tested and adjusted to higher values as follows:

1. Press "Edit" to the right of "Strength".

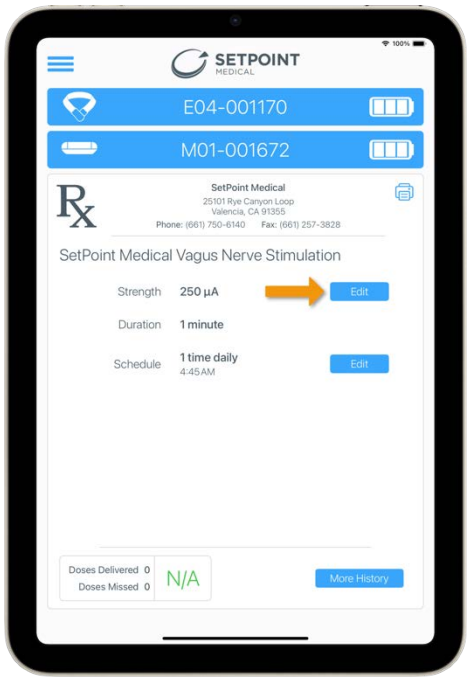


Figure 58 - Press "Edit" to the right of "Strength" to adjust the dose strength.

2. The default dose strength is 250 µA for all new prescriptions. Press “+” to increase the dose strength in increments of 50 µA or “-” to decrease the dose strength in increments of 50 µA. Programmer will limit dose strength increases to 250 µA prior to testing. The maximum dose strength is 2,500 µA, but you should stop when the maximum tolerated dose is achieved.

Figure 59 - Press "+" and "-" to modify dose strength.

3. Instruct the patient that testing is about to begin and that they should inform you of any discomfort. Stimulation can be stopped by pressing “Reject” in Programmer or by unlatching the Charger. If the Charger is unlatched, it can be relatched without automatically resuming stimulation.
4. Once a desired dose strength is set, press “Test Dose Strength” to initiate the test stimulation. The Charger will briefly sound a **rapid beep** pattern, and the Charger LED will **blink white** to indicate that stimulation is starting.

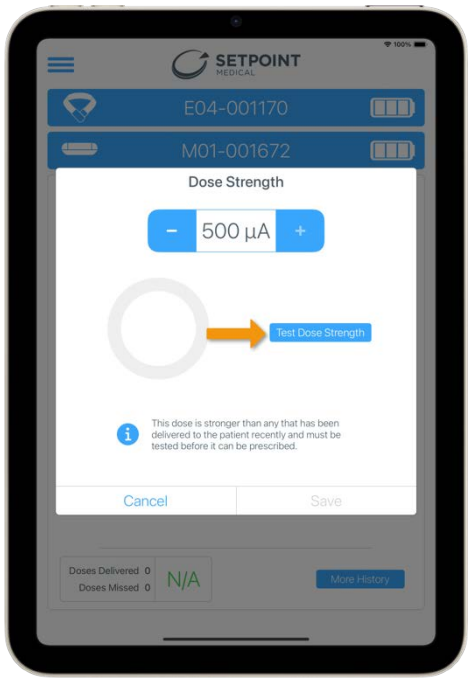


Figure 60 - Press "Test Dose Strength" to begin stimulation.

5. To be accepted, the test dose must be delivered for at least 15 seconds. If at any time the patient experiences discomfort, press “Reject” or unlatch the Charger. Note that the patient may or may not feel the test stimulation. Unless stopped, the test dose will be delivered for a total of 60 seconds.

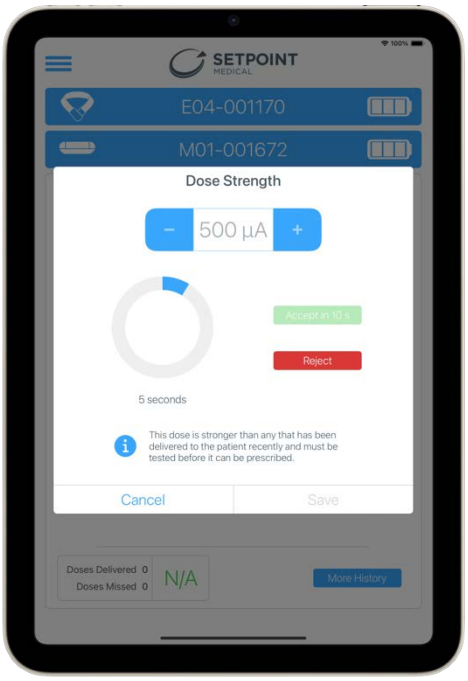


Figure 61 - A test dose may not be accepted until stimulation has occurred for at least 15 seconds. The test dose may be stopped at any time by pressing "Reject".

6. If the tested dose strength is deemed comfortable after at least 15 seconds of stimulation, press “Accept”.

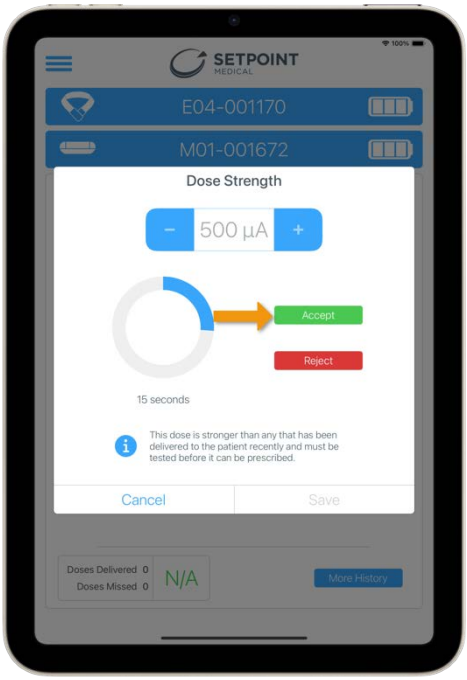


Figure 62 - The test dose may be accepted if at least 15 seconds of stimulation has elapsed, and the patient does not indicate discomfort.

7. The dose strength can be further adjusted and re-tested if needed by repeating steps 2-6.
8. Once the optimal dose strength has been determined, it can be saved as a new prescription by pressing “Save”.

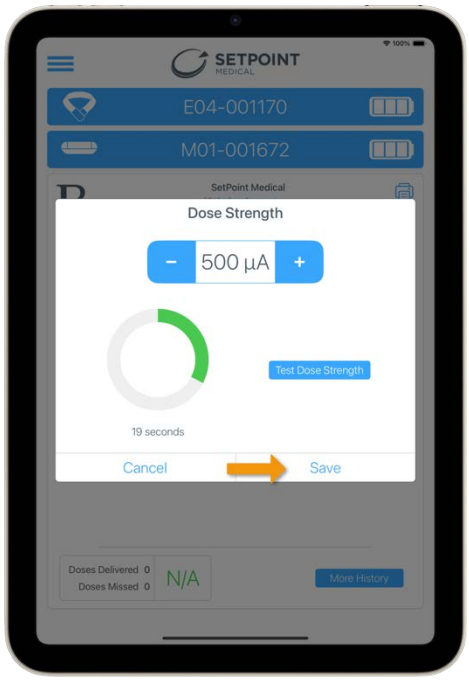


Figure 63 - Pressing "Save" will program a new prescription on the patient's Implant.

Editing Dose Schedule

The default time for stimulation will automatically be programmed for all patients. To adjust the stimulation time from the default, proceed as follows:

1. Press “Edit” to the right of “Schedule”.

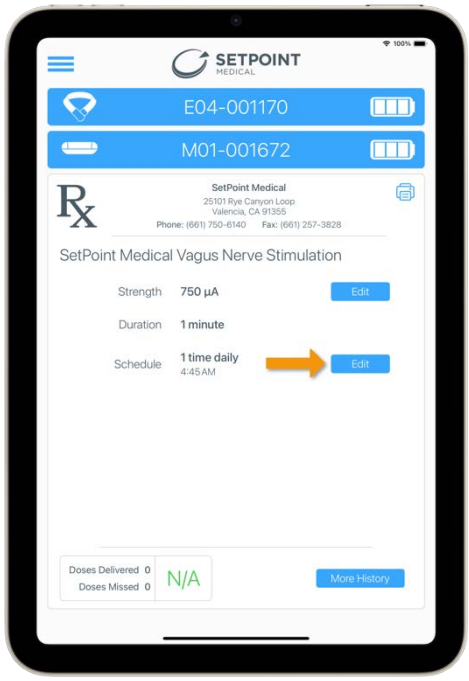


Figure 64 - Press "Edit" to the right of "Schedule" to adjust the dose schedule.

9. Move the time indicator to the desired time. Dose time may be set in increments of 15 minutes. Once the dose time has been adjusted, it can be saved to a new prescription by pressing “Save”. Note that small variations in dose delivery times are to be expected and will be corrected when the Charger is used to Charge the Implant.

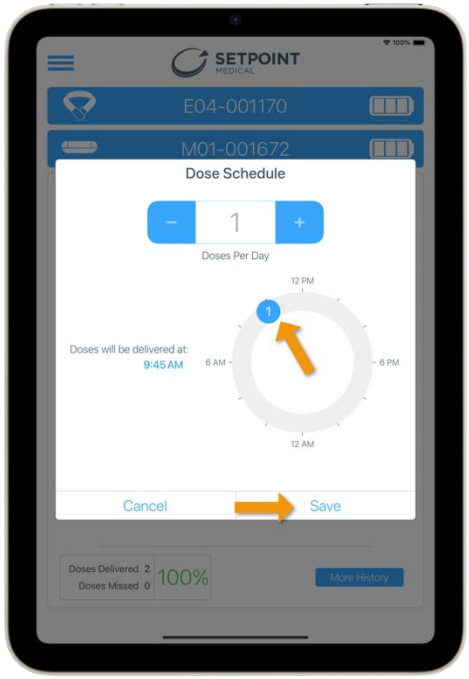


Figure 65 – Move the time indicator to modify the scheduled dose time.

Patient Prescription History

Programmer displays information about the patient’s prescription history, including percentage of scheduled doses delivered. A percentage less than 100% could occur if the Implant has been suspended or if the Implant’s battery has been depleted. Automatic doses will not be delivered while the Charger is being worn, either during a clinic visit or while charging at home.

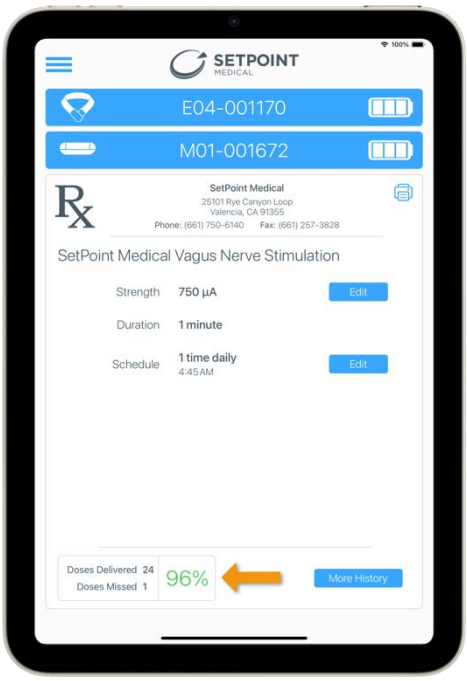


Figure 66 – History of the Current Prescription

Pressing “More History” allows you to view past prescriptions, including the dates the prescriptions were created, the dosing parameters, and the number of doses that were delivered or missed in the timeframe during which that prescription was active.

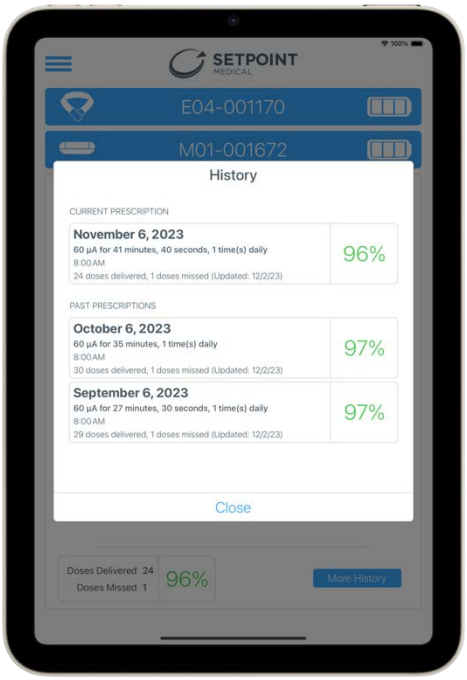


Figure 67 - Prescription History for the Connected Implant

Prescription history may be printed, if an AirPrint®-compatible printer is available on the same Wi-Fi network, by pressing the printer icon on the top-right of the Prescription Panel. For additional support on printing, refer to the iPad Owner’s Manual, or check Apple support at https://support.apple.com.

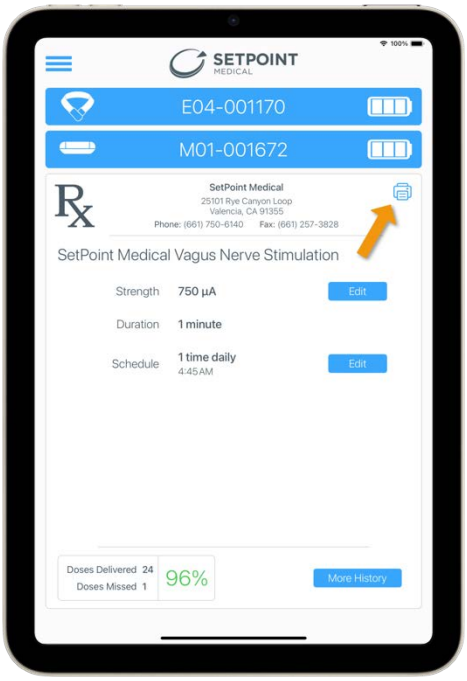


Figure 68 - Press the printer icon in the top-right corner of the Prescription Panel to print.

Prescription history can also be viewed even when the patient is not in the clinic.

1. Press the menu icon in the upper left of the Programmer and then press “History”.

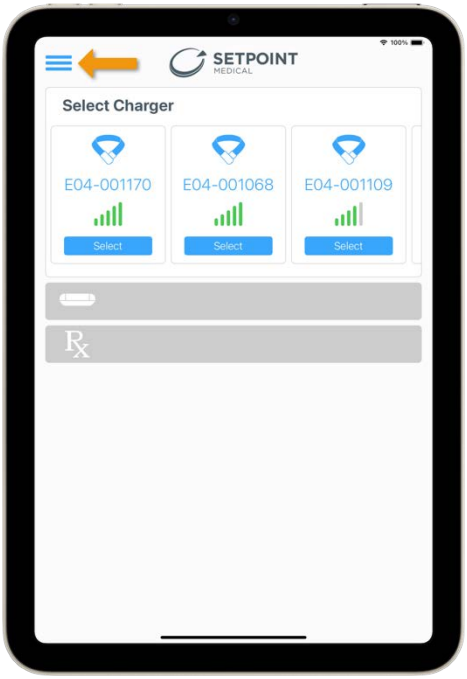


Figure 69 – Menu Icon

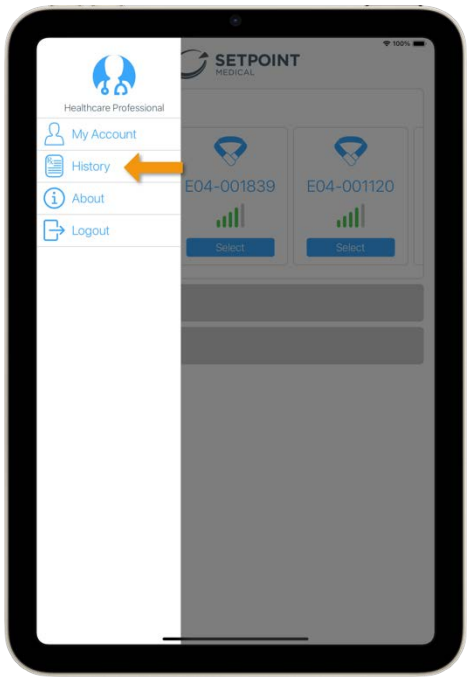


Figure 70 – Press "History" to retrieve prescription history.

2. A list of all the Implants that have been programmed by the clinic will appear. Press the patient's Implant to view its prescription history.

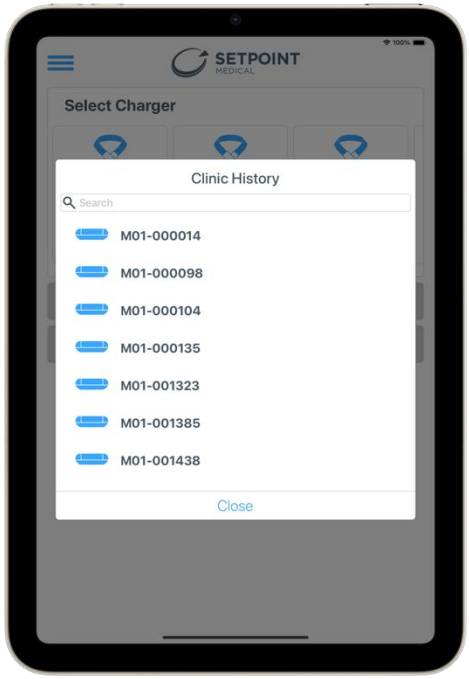


Figure 71 - All Implants Programmed by the Clinic

Suspending Therapy

Programmer can be used to temporarily suspend daily stimulation if needed. Therapy can only be resumed by a healthcare professional using Programmer.

1. Press the Implant Panel.

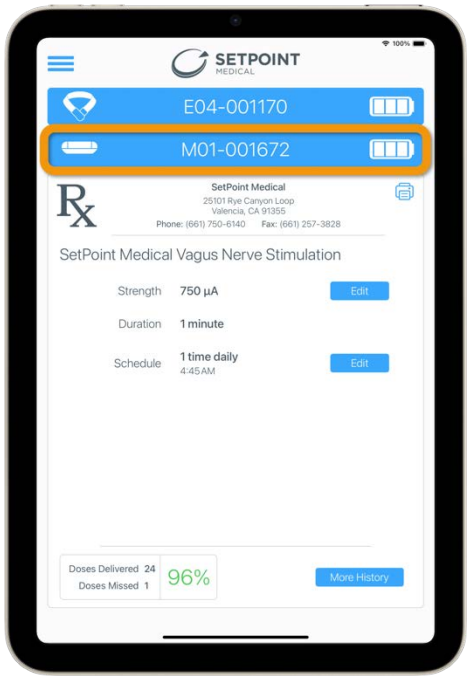


Figure 72 - Press the Implant Panel.

2. Press “Suspend Therapy”.

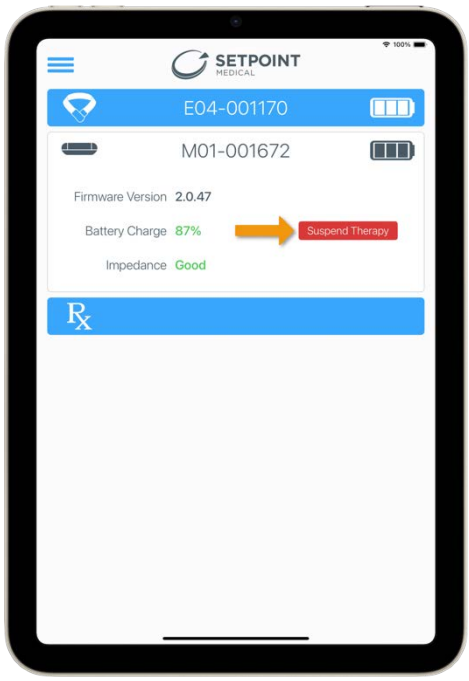


Figure 73 - Press "Suspend Therapy".

3. When prompted, press “Suspend” to confirm.

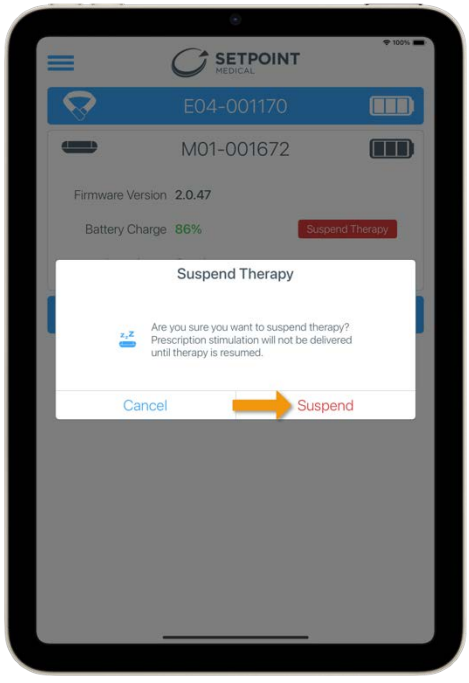


Figure 74 - Press "Suspend" to confirm therapy suspension.

4. Ensure the Charger LED shows solid **pink** to confirm therapy has been suspended.

Resuming Therapy

Programmer can be used to resume daily stimulation after temporary suspension.

1. Press the Implant Panel or the Prescription Panel.
2. Press “Resume Therapy”.

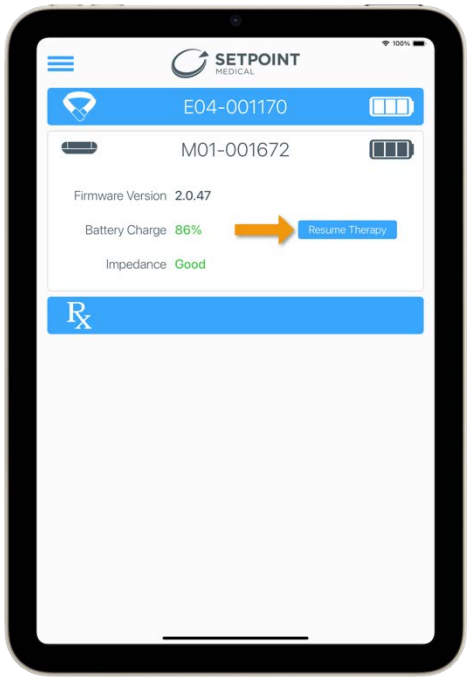


Figure 75 - From the Implant Panel, press the "Resume Therapy" button to allow the Implant to resume delivering stimulation.

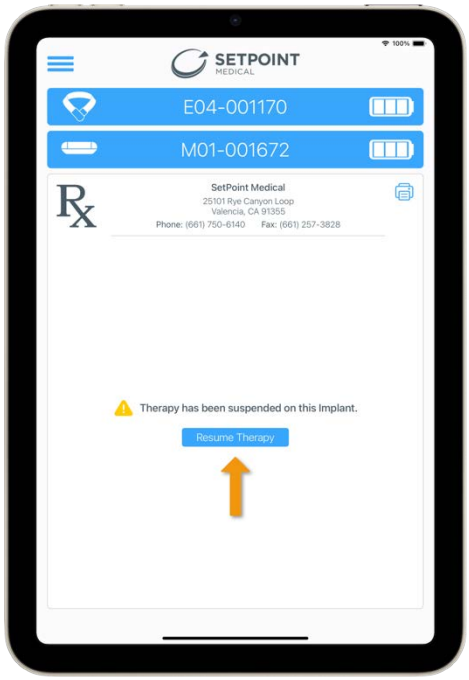


Figure 76 - From the Prescription Panel, press the "Resume Therapy" button to allow the Implant to resume delivering stimulation.

3. When prompted, press “Resume” to confirm.

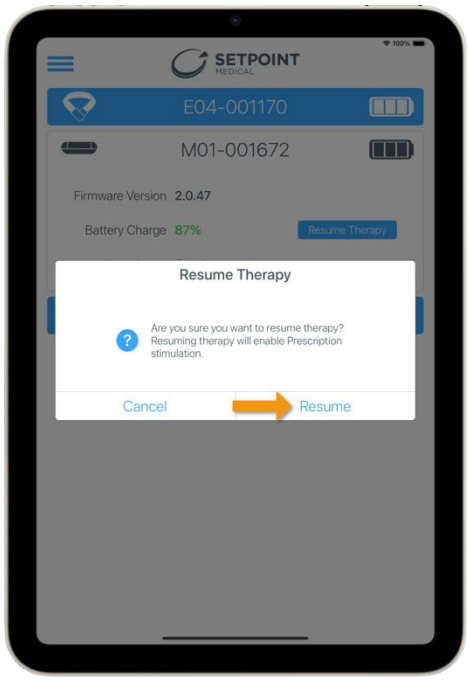


Figure 77 - Press "Resume" to confirm resumption of therapy.

4. Confirm that the prescription that was previously set, prior to suspending therapy on the Implant, is displayed in the Prescription Panel.

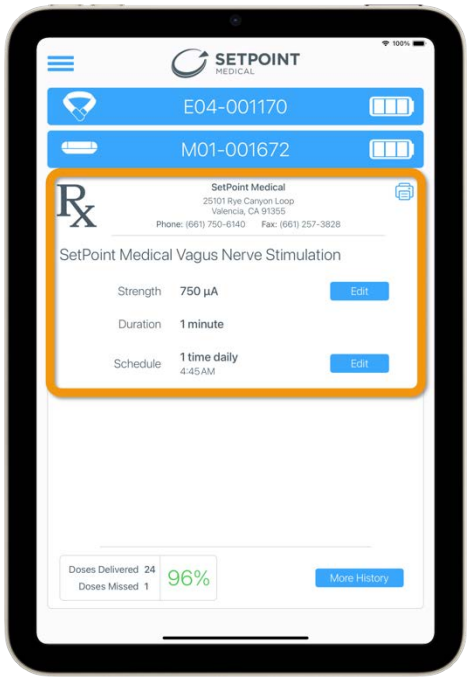


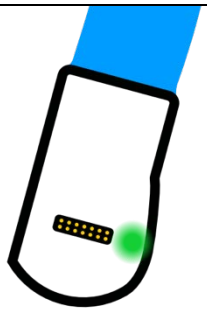
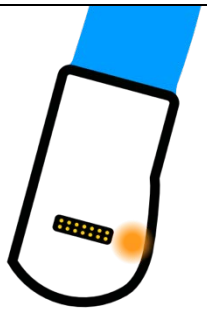
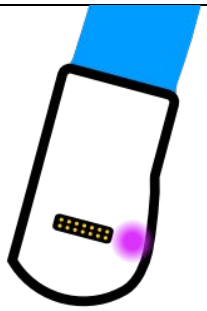
Figure 78 - Programmer will show the previously set prescription when therapy is resumed.

5. Ensure the Charger LED shows **green** or **orange** to confirm therapy has been resumed.

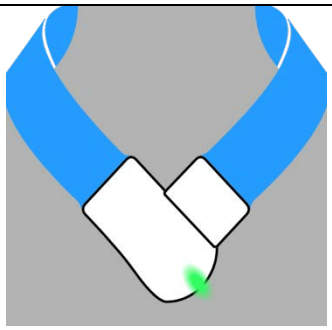
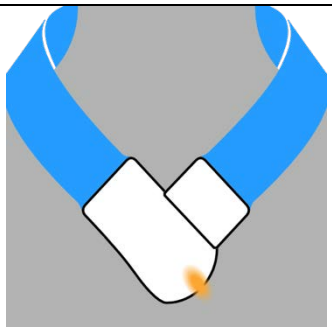
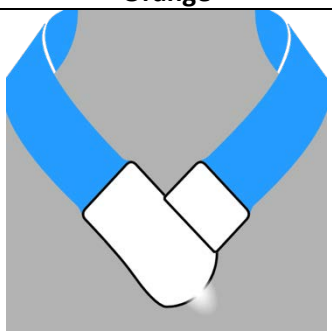
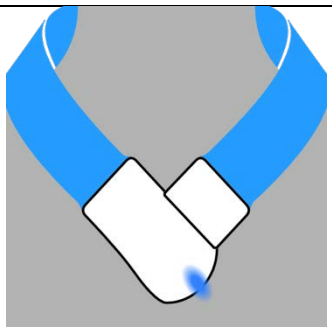
Appendix A - Charger LED Status

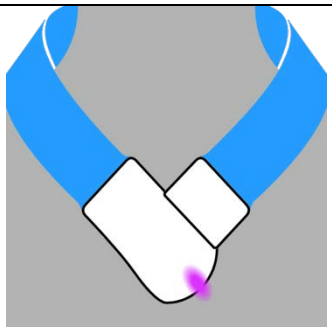
The LED on the Charger will show different things based on how it is being used.

While Unlatched

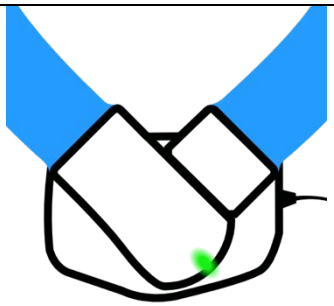
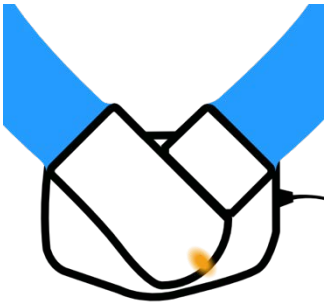
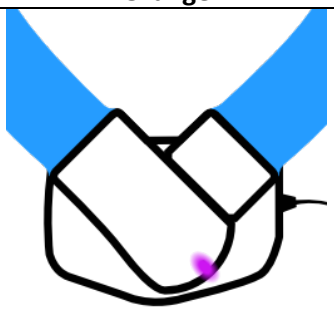
LED Color	Status
 **Green**	**Solid**: The Charger has enough charge to charge the Implant.
 **Orange**	**Solid**: The Charger does not have enough charge to charge the Implant. **Blink**: The Charger needs to be charged before it can be used, or it will turn off.
 **Pink**	**Slow Blink**: This is a warning. The Charger might be too hot. Make sure to keep it in a cool place and away from direct sunlight. **Rapid Blink**: The Charger has an error that cannot be fixed. Stop using it and call SetPoint Medical.

While Being Worn

LED Color	Status
 **Green**	**Solid**: The Implant is fully charged. **Blink**: The Implant has enough charge.
 **Orange**	**Solid**: The Implant is not fully charged and has not started charging yet. **Blink**: The Implant is charging but is not full yet.
 **White**	**Slow Pulse**: The Charger is trying to connect to the Implant. **Rapid Blink**: The Implant is delivering a dose and charging will start once it is complete.
 **Blue**	**Rapid Blink**: A Bluetooth connection to the Charger is waiting for confirmation. **Periodic Blink**: There is an established Bluetooth connection to the Charger. This periodic blink will alternate with other Charger LED states.

LED Color	Status
 **Pink**	**Solid**: The Implant is suspended and will not deliver doses. **Slow Blink**: This is a warning. • The band of the Charger might be twisted or bent. Make sure it is being worn it correctly. • The Charger might be too hot. Make sure to keep it in a cool place and away from direct sunlight. • There might be dirt or lint on the Charger's magnetic latch. Look at the **Cleaning** section in the guide for how to clean the latch. **Rapid Blink**: The Charger has an error that cannot be fixed. Stop using it and call SetPoint Medical.

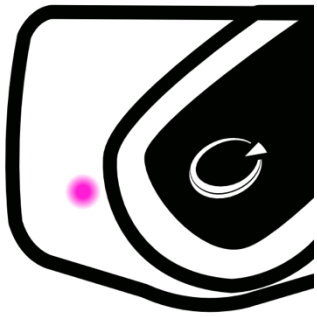
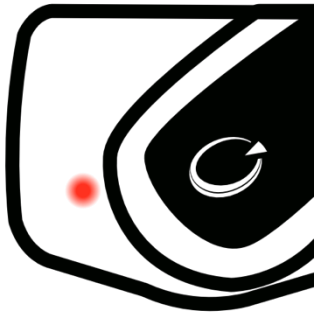
While on the Docking Station

LED Color	Status
 **Green**	**Solid**: The Charger is fully charged. **Blink**: The Charger has enough charge to charge the Implant.
 **Orange**	**Blink**: The Charger is charging, but not full enough to charge the Implant.
 **Pink**	**Slow Blink**: This is a warning. • The Charger may not be closed properly. The Charger cannot charge if it is not latched. • The Charger might be too hot. Make sure to keep it in a cool place and away from direct sunlight. **Rapid Blink**: The Charger has an error that cannot be fixed. Stop using it and call SetPoint Medical.

Appendix B – Charger Speaker Status

Sound Pattern	Status
Two Beeps That Go *Up* in Tone	The Charger is now connected to the Implant.
Two Beeps That Go *Down* in Tone	The Charger has lost its connection with the Implant.
Single Long Beep	A BLE connection has been established between the Charger and Programmer.
Rapid Repeating Beep	The Implant has started test stimulation.
Medium Repeating Beep	The connection between the Charger and the Implant is not strong enough to start charging.
Three Beeps That Go *Up* in Tone	The Implant has started charging.
Four Beeps, Three Beeps That Go *Up* in Tone and a Fourth Beep That is a Repeat of the Last Tone	The Implant has finished charging.

Appendix C – Docking Station LED Status

LED Color	Indicator Status
 **Blue**	**Solid**: The Charger is fully charged. **Blink**: The Charger is charging.
 **Pink**	**Solid**: The Docking Station is ready for use, but the Charger is not charging.
 **Red**	**Blink**: The Docking Station has an error. • Remove the Charger from the Docking Station. • Check that there are no metal objects on or around the Docking Station. • Place the Charger on the Docking Station again. • Check that the Charger is closed. If the error continues, stop using the Docking Station, and contact SetPoint Medical.

Appendix D – Troubleshooting

Docking Station

Event	Cause and Resolution
The Docking Station does not show a **pink** LED when plugged in.	The Docking Station is not getting power. Check if the outlet it is plugged into is working (it is turned on, the GFI is not tripped, and the wall switch is on). If the outlet is fine but the problem continues, contact SetPoint Medical.
The Docking Station is **blinking red** on its LED.	This is a warning. • Check that the Charger is closed. • Check that there are no metal objects on or around the Docking Station. The Docking Station cannot charge if there are metal objects present. • The Charger and/or Docking Station might be too hot and cannot charge. Make sure to keep them in a cool place and away from direct sunlight. • Take off the Charger for a few seconds, then put it back on the Docking Station cradle. Sometimes, if it wasn't placed or seated correctly, it can stop the Charger and Docking Station from charging. If the error continues, stop using the Docking Station, and contact SetPoint Medical.
The Docking Station shows a **pink** LED when the Charger is placed on it.	If this persists and the LED never turns **blue**, the connection between the Charger and your Docking Station cannot be established. This could be caused by electromagnetic interference. Try changing your location, waiting until a later time, or turning off the suspected source of interference if possible. If using portable RF communications equipment, make sure they are no closer than 12 inches (30 cm) to any part of the Charger or Docking Station.

Charger

Event	Cause and Resolution
The Charger is **slowly blinking pink** on its LED.	This is a warning. • The Charger may not be closed properly. The Charger cannot charge if it is not latched. • The Charger might be too hot. Make sure to keep it in a cool place and away from direct sunlight. • The band of the Charger might be twisted or bent. Make sure to wear it correctly. • There might be dirt or lint on the Charger's latch. Look at the **Cleaning** section in the guide for how to clean the latch. If the Charger continues to **slowly blink pink**, contact SetPoint Medical.
The Charger is **rapidly blinking pink** on its LED.	The Charger has an error that cannot be fixed. Stop using it and call SetPoint Medical.
The Charger shows a **solid pink** LED.	The Implant is suspended and will not deliver doses. Use the Programmer to resume therapy if desired.
The Charger sounds a repeated beeping tone when worn.	The connection between the Charger and the Implant is not strong enough to start charging. The band of the Charger might be twisted or bent. Make sure it is being worn correctly. If the Charger continues the repeated beeping pattern, contact SetPoint Medical.
The Charger **slowly pulses white** on its LED when worn.	If this persists and the connection beeps never play, the connection between the Charger and the Implant cannot be established. This could be caused by electromagnetic interference. Try changing the patient's location, waiting until a later time, or turning off the suspected source of interference if possible. If using portable RF communications equipment, make sure they are no closer than 12 inches (30 cm) to any part of the Charger. Also check the area for other Chargers.
The Charger is **blinking** or **solid blue** on its LED, but Programmer does not display the Charger.	Programmer on a different iPad is trying to connect or is connected to the Charger. Check the area for other Programmers.

Programmer

Error Message	Cause and Resolution
Network	
Connection Error SetPoint Programmer experienced an issue with connectivity. Check your network connection and contact SetPoint Medical if the issue persists.	Programmer lost connection with SetPoint Medical's cloud services due to internet connectivity issues. Follow the procedure in the section **Troubleshooting Network Connectivity**.
Network connection unavailable.	Programmer was not able to communicate with SetPoint Medical's Cloud services due to Internet connectivity issues. Follow the procedure in the section **Troubleshooting Network Connectivity**.
There was an error communicating with SetPoint Medical. Please check your Internet connectivity.	
Login	
Your email address needs to be verified to log in. Check your inbox for a confirmation email. If you need a new email sent, use "Forgot Password" to send a password reset email to verify your email address.	The email address for a SetPoint Medical account has not yet been verified. Follow the procedure in steps 5 and 6 in the section **Creating an Account**.
Login failed. Please try again.	Programmer could not connect with SetPoint Medical's cloud services due to internet connectivity issues. Follow the procedure in the section **Troubleshooting Network Connectivity**.
Login failed. Invalid credentials.	Invalid credentials were entered. Re-enter your email, password, and multi-factor authentication. If a password reset is needed, follow the procedure in the section **Resetting Password**. Contact SetPoint Medical to reset multi-factor authentication, if necessary.
The user credentials provided are not for the currently logged-in user.	The username or password does not match that for the current user. Check and re-enter the correct credentials.
The attempt to log in with your Microsoft ID failed.	Login with Microsoft was not successful.
Too many text message requests have been made. Please wait or try another form of authentication.	More than 10 text messages were sent within 1 hour. Wait one hour or use a different multi-factor authentication method, if available. Contact SetPoint Medical to reset multi-factor authentication, if necessary.

Error Message	Cause and Resolution
Your account has not been authorized to use SetPoint Programmer. Healthcare professionals should contact SetPoint Medical to obtain authorization.	The account has not been approved for Programmer use by SetPoint Medical. Follow the procedure in step 7 in the section **Creating an Account**.
Bluetooth	
Bluetooth has been disabled for SetPoint Programmer. Please enable Bluetooth in SetPoint Programmer settings.	Programmer access to Bluetooth is not allowed. Press "Open Settings", and then allow Programmer access to Bluetooth.
Bluetooth has been disabled on this iPad. Please enable Bluetooth in Settings.	iPadOS access to Bluetooth is not allowed. 1. Return to the home screen. 2. Open the "Settings" application. 3. Navigate to the Bluetooth Settings for iPadOS and enable Bluetooth.
"Programmer" would like to use Bluetooth for new connections You can allow new connections in Settings.	New Bluetooth connections have been turned off from Control Center. Press "Settings", and then press "Allow New Connections" to enable Bluetooth.
Turn on Bluetooth to Allow "Programmer" to Connect to Accessories	iPadOS access to Bluetooth is not allowed. Press "Settings", and then enable Bluetooth.
Charger	
Charger Authentication Error SetPoint Programmer encountered an error attempting to authenticate the Charger (E04-XXXXXX). Please contact SetPoint Medical.	Programmer cannot verify the authenticity of the Charger. Contact SetPoint Medical.
Charger disconnected. Make sure the Charger is charged and nearby.	Programmer has lost connection with the Charger, and the Charger is no longer available for a Bluetooth connection. Follow the procedure in the section **Troubleshooting Programmer and Charger Connection**.
Invalid Charger Use The connected Charger is designated for Engineering use, but the Implant is not. Please contact SetPoint Medical.	The Charger has been detected but is designated for internal SetPoint Medical use only. Contact SetPoint Medical.

Error Message	Cause and Resolution
Unregistered Charger The selected Charger (E04-XXXXXX) has not been registered with SetPoint Medical and was disconnected. Please contact SetPoint Medical.	The Charger needs to be registered in the SetPoint Medical database prior to use. Contact SetPoint Medical.
Implant	
Implant Authentication Error SetPoint Programmer encountered an error attempting to authenticate the Implant (M01-XXXXXX). Please contact SetPoint Medical.	Programmer cannot verify the authenticity of the Implant. Contact SetPoint Medical.
Prescription Delivery Not Confirmed The last Prescription for Implant M01-XXXXXX may not have been programmed. Please ensure the Prescription was programmed.	The Implant may have been disconnected before the prescription was written. Reconnect to the Implant to allow the prescription to be written. If the latest prescription is not shown, rerun test doses as needed and save the prescription.
This Implant (M01-XXXXXX) has not yet been enrolled in a study. Please contact SetPoint Medical.	The Implant is designated to participate in a study but has not been assigned to a study cohort. Contact SetPoint Medical.
This Implant (M01-XXXXXX) has not been registered with SetPoint Medical. Please contact SetPoint Medical.	The Implant needs to be registered in the SetPoint Medical database prior to use. Contact SetPoint Medical.
The patient's prescription is currently being delivered. Connection will continue when the dose is finished.	The Implant has been detected, but the automatic dose is being delivered. Please wait for stimulation to complete and the connection will be resumed.
Therapy Suspend/Resume Not Confirmed The request to suspend/resume therapy for Implant M01-XXXXXX was not confirmed. Please ensure the therapy status is correct.	The Implant may have been disconnected before therapy was suspended or resumed. Reconnect to the Implant to allow the therapy state to be written.

Error Message	Cause and Resolution
Programmer	
This version of SetPoint Programmer is out-of-date and must be updated before logging in. Please contact SetPoint Medical for assistance.	An updated version of the Programmer application has been released. Upgrade to the latest version to proceed. For additional support on updating, refer to the iPad Owner's Manual, or check Apple support at https://support.apple.com.

Troubleshooting Network Connectivity

1. Retry the activity in case there was a temporary interruption in internet connectivity.
2. Ensure Wi-Fi/cellular service is connected. For additional support on network connectivity, refer to the iPad Owner's Manual, or check Apple support at https://support.apple.com.
3. Open Safari and navigate to https://setpointmedical.com/.
    a. If you can connect to the website, work with your IT department to configure the network to allow Programmer to access SetPoint Medical. Please refer to the **SetPoint IT Configuration Guide**.
    b. If you cannot connect to the website, restart the iPad. If the issue persists, contact your IT department to troubleshoot general network issues.

Troubleshooting Programmer and Charger Connection

1. Ensure the Charger is on by tapping the magnetic latch and observing the LED. If the LED does not illuminate, place it on the Docking Station to wake it up.
2. If the Charger LED is **blinking blue**, but the Charger is not connected in Programmer, this indicates it is connected to another Programmer. Determine which Programmer is connected and instruct them to disconnect from the Charger.
3. If connection issues to the Charger persist, contact SetPoint Medical for further troubleshooting.

Appendix E – Explanation of Symbols Used on Packaging and Devices

Symbol	Title	Reference	Description
21 CFR 801.109: Prescription Devices			
	Prescription Only	(b) (1)	Caution: Federal law restricts this device to sale by or on the order of a physician
47 CFR 2.1074: Identification			
	FCC Declaration of Conformity	(b)	The product complies with the applicable FCC requirements
ASTM F2503			
	Magnetic Resonance (MR) Conditional	Fig. 5	An item with demonstrated safety in the MR environment within defined conditions including conditions for the static magnetic field, the time-varying gradient magnetic fields and the radiofrequency fields
	Magnetic Resonance (MR) Unsafe	Fig. 9	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment
WEEE Directive 2012/19/EU			
	Symbol for the marking of EEE	Annex IX	Separate collection for electrical and electronic equipment
IEC 60417			
	Non-ionizing Electromagnetic Radiation	5140	To indicate elevated, potentially dangerous, levels of non-ionizing radiation
	Class II Equipment	5172	To identify equipment meeting the safety requirements specified for Class II equipment according to IEC 61140
	For Indoor Use Only	5957	To identify electrical equipment designed primarily for indoor use
IEC 60529			
IP21	Degree of Protection	N/A	Protected against solid foreign objects of 0.5 in (12.5 mm) Ø and greater; Protection against vertically falling water drops.
IP22	Degree of Protection	N/A	Protected against solid foreign objects of 0.5 in (12.5 mm) Ø and greater; Protection against vertically falling water drops when enclosure is tilted up to 15°.
International Efficiency Marking Protocol for External Power Supplies			
	International Efficiency Marking Level VI	N/A	Mark indicating EPS meets the level VI requirements at both 115 V/60 Hz and 230 V/50 Hz
ISO 15223-1: 5.1. Manufacture			
	Manufacturer	5.1.1	Indicates the medical device manufacturer

	Date of Manufacture	5.1.3	Indicates the date when the medical device was manufactured
	Use-By Date	5.1.4	Indicates the date after which the medical device is not to be used
	Catalog Number	5.1.6	Indicates the manufacturer's catalog number so that the medical device can be identified
	Serial Number	5.1.7	Indicates the manufacturer's serial number so that a specific medical device can be identified
	Model Number	5.1.10	Indicates the model number or type number of a product
ISO 15223-1: 5.2. Sterility			
	Do Not Use If Package Is Damaged and Consult Instructions for Use	5.2.8	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
ISO 15223-1: 5.3. Storage			
	Temperature Limit	5.3.7	Indicates the temperature limits to which the medical device can be safely exposed
	Humidity Limitation	5.3.8	Indicates the range of humidity to which the medical device can be safely exposed
	Atmospheric Pressure Limitation	5.3.9	Indicates the range of atmospheric pressure to which the medical device can be safely exposed
ISO 15223-1: 5.7. Others			
	Unique Device Identifier	5.7.10	Indicates a carrier that contains unique device identifier information
ISO 7010			
	Refer to Instruction manual/booklet	M002	To signify that the instruction manual/booklet must be read
	General Warning Sign	W001	To signify a general warning
UL Solutions Marks and Label Hub			
	UL Recognized Component Mark for US and Canada	N/A	Tested and certified in accordance with applicable US and Canadian electrical safety and performance standards
Electrical Appliances and Materials Safety Act			

	TÜV SÜD PSE Diamond Mark	N/A	Tested and certified in accordance with applicable Japanese electrical safety and performance standards for Specified Electrical Appliances and Materials

Applicable Standards and Regulations

21 CFR 801 Medical Devices – Labeling

47 CFR 2 Frequency Allocations and Radio Treaty Matters: General Rules and Regulations – Equipment Authorization Procedures

ASTM F2503 – 23 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE)

Electrical Appliances and Materials Safety Act Statutory Operations and Implementation Guide (ver. 4.0)

IEC 60417:2024 Graphical Symbols for use on Equipment

IEC 60529:1989/AMS2:2013/COR1:2019 Degrees of protection provided by enclosures (IP Code)

International Efficiency Marking Protocol for External Power Supplies Version 3.0, September 2013

ISO 15223-1:2021 Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements

ISO 7010:2019 Graphical symbols – Safety colors and safety signs – Registered safety signs

Appendix F – SetPoint System Technical Description

Implant

Power Source

The Implant is internally powered by a rechargeable battery.

Characteristic	Value
Type	Secondary (Rechargeable)
Chemistry	Lithium-ion (Li-ion)
Form Factor	Cylindrical
Voltage	4.0 V (Nominal)
Capacity	3.0 mAh
Safety Features	Zero-Volt Technology

Table 3 – Implant Battery Characteristics

The rechargeable battery is rated to last for 10 years, and this duration is not impacted by any Implant settings, (e.g., the strength or timing of stimulation).

Charger

⚠ **Warning:** Do not modify or tamper with the SetPoint Charger. If you do, it could alter its function or bypass safety features and result in harm.

Classification

Per IEC 60601-1, the Charger does not meet the definition of an Applied Part, only of an Accessible Part. Per clause 4.6, and per risk assessment, it was, however, tested to the more rigorous Applied Part requirements. The table below shows the relevant technical classifications for the Charger per IEC 60601-1 and collateral standards.

Classification	Value
Accessibility	Type BF, Applied Part
Power Source	Internally Powered
Mode of Operation	Continuous
Operating Environment	Home Healthcare
Transportability	Body-Worn
Transit Operability	Transit-Operable
Ingress Protection	IP22

Table 4 – Charger As-Tested Classifications

Per IEC 60601-1, the user is classified as a Patient only while the Charger is latched around their neck, and as an intended Operator while placing or removing the Charger around their neck or onto or from the Docking Station.

Power Source

The Charger is internally powered by a non-replaceable, rechargeable battery.

Characteristic	Value
Type	Secondary (Rechargeable)
Chemistry	Lithium-ion (Li-ion)
Form Factor	Pouch

Voltage	3.7 V (Nominal)
Capacity	1.0 Ah
Safety Features	Over Charge, Over Discharge, and Over Current Detection

Table 5 – Charger Battery Characteristics

On a full charge, the rechargeable battery can power the Charger for 20 to 60 minutes depending on the placement of the Charger around the neck and how optimally it is communicating with the Implant. The rechargeable battery is rated to last for 5 years, and this duration is not impacted by how the Charger is used.

Radios

The Charger contains a Bluetooth Low Energy (BLE) radio receiver that receives RF electromagnetic energy in the frequency range 2.400 GHz to 2.4835 GHz. The Charger also contains two radios, one BLE and one inductive, that transmit electromagnetic energy as follows:

Characteristic	Value	
	BLE Radio	**Inductive Radio**
Frequency Range	2.400 GHz – 2.4835 GHz	127.6 kHz – 134.4 kHz
Modulation Type	GFSK, 1Mbps	AM 2400 bps
EIRP	2.5 mW (+4 dBm)	Not Defined, Total Power ≤ 6 W

Table 6 - Radio Transmit Details

Product Markings

All Charger product markings are contained on the Charger label shown below (artwork shown is for reference only).

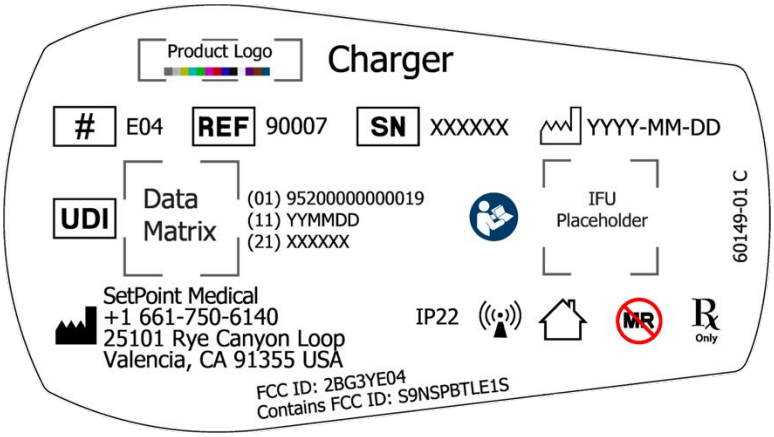


Figure 79 – Charger Label

Docking Station

⚠ **Warning:** Do not modify or tamper with the SetPoint Docking Station. If you do, it could alter its function or bypass safety features and result in harm.

Classification

The table below shows the relevant technical classifications for the Docking Station per IEC 60601-1 and collateral standards.

Classification	Value
Accessibility	Accessible Part
Power Source	Externally Powered Class II
Mode of Operation	Continuous
Operating Environment	Home Healthcare
Transportability	Portable
Transit Operability	Non-Transit-Operable
Ingress Protection	IP21

Table 7 – Docking Station Classifications

Per IEC 60601-1, the user is classified as an intended Operator while placing or removing the Charger onto or from the Docking Station.

Power Source

The Docking Station is externally powered through a power supply cord to a power supply with a mains-plug that can be removed from the mains socket-outlet to provide supply mains isolation. This non-detachable power supply cord is not replaceable.

Characteristic	Value
Input Type	AC
Input Voltage	100-240 VAC
Input Frequency	50-60 Hz
Input Max Current	1.0-0.5 A
Output Type	DC
Output Voltage	5 V
Output Max Current	2.4 A

Table 8 – Docking Station Power Supply Performance Characteristics

Product Markings

All Docking Station product markings are contained on the Docking Station and power supply labels shown below (artwork shown is for reference only).

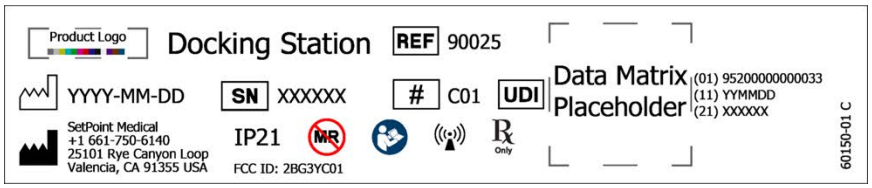


Figure 80 – Docking Station Label

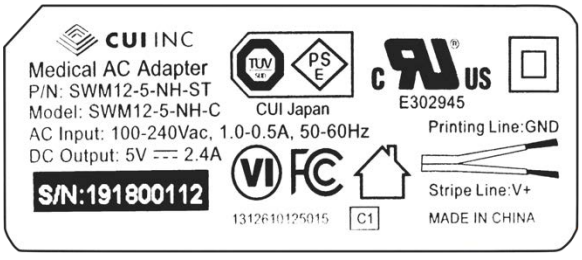


Figure 81 – Docking Station Power Supply Label

Charger and Docking Station

Emissions and Immunity Testing

The Charger and Docking Station are classified as CISPR 11 Class B Group 2 emitters. Both devices were tested with immunity test levels for use in a home healthcare environment. They were found to comply with the following immunity test standards at the specified test levels:

IEC 61000-4-2 – Charger and Docking Station Electrostatic Discharge

Device	Contact Discharge (± kV)	Air Discharge (± kV)
Charger	8	2, 4, 8, 15
Docking Station	N/A	

Table 9 - IEC 61000-4-2 Test Details

IEC 61000-4-3 – Charger and Docking Station RF EM Fields and Proximity Fields from RF Wireless Communications Equipment

- Radiated RF EM Field Exposures: 10 V/m from 80 MHz – 2.7 GHz w/80% Amplitude Modulation @1 kHz
- Proximity Field Exposures:

Test Frequency (MHz)	Modulation	Immunity Test Level (V/m)
385	Pulse, 18 Hz	27
450	Pulse, 18 Hz	28
710, 745, 780	Pulse, 217 Hz	9
810, 870, 930	Pulse, 18 Hz	28
1720, 1845, 1970, 2450	Pulse, 217 Hz	28
5240, 5500, 5785	Pulse, 217 Hz	9

Table 10 - IEC 61000-4-3 Test Details (Pulse = 50% Square Wave Duty Cycle)

IEC 61000-4-4 – Docking Station EFT/Burst

- ± 2 kV @100 kHz Repetition Frequency

IEC 61000-4-5 – Docking Station Line to Line Surge

- ± 0.5 kV and ± 1 kV

IEC 61000-4-6 – Docking Station Conducted Disturbances

- 3 V_{rms} from 150 kHz – 80 MHz
- 6 V_{rms} from 150 kHz – 80MHz for ISM and Amateur Radio Bands w/80% Amplitude Modulation @1 kHz

IEC 61000-4-8 – Charger and Docking Station Rated Power Frequency Magnetic Field

- 30 A/m @60Hz

IEC 61000-4-11 – Docking Station Voltage Dip and Interruption

- 100 VAC and 240 VAC @60 Hz

Voltage Level	Duration (cycles)	Phase Angle
0% of U_t	0.5	0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°

0% of U_t	1	0°
70% of U_t	30	0°
0% of 120 V	300	0°

Table 11 - IEC 61000-4-11 Test Details (U_t = 100 V or 240V)

IEC 61000-4-39 – Charger and Docking Station Proximity Magnetic Field

Test Frequency	Modulation	Immunity Test Level (/m)
30 kHz	CW	8
134.2 kHz	Pulse, 2.1 kHz	65
13.56 MHz	Pulse, 50 kHz	7.5

Table 12 - IEC 61000-4-39 Test Details (Pulse = 50% Square Wave Duty Cycle)

FCC Compliance

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Changes or modifications not expressly approved by SetPoint Medical could void your authority to operate the equipment.

To maintain compliance with the FCC's RF exposure guidelines, the Docking Station should be installed and operated with a minimum distance of 8 in (20 cm) between it and your body.

Appendix G – Clinical Studies Safety

Adverse Events

Adverse events are side effects, complications, or discomforts related to a procedure or treatment. This Appendix describes adverse events associated with the SetPoint system that may occur during the surgery to insert or remove the Implant or associated with stimulating the vagus nerve (referred to as vagus nerve stimulation or VNS)

Clinical Studies

The SetPoint System has been evaluated in two U.S. clinical studies enrolling 257 patients (the pilot study enrolled 15 patients and RESET-RA enrolled 242 patients). Adverse events reported by the study doctor as related to either the surgery or stimulation associated with the SetPoint System are summarized below.

At the time of FDA review for the SetPoint System, patients on average had been living with the Implant and receiving stimulation for longer than 1 year, with some patients, those enrolled in the pilot study, receiving treatment for over 5 years.

Nearly all adverse events reported during the clinical studies were mild to moderate in severity, and nearly all adverse events were considered non-serious by the study doctor (98% non-serious). No patients during the study experienced a life-threatening complication related to the SetPoint System, and no deaths were reported for any cause. During the clinical studies, no new safety issues were identified.

Surgery (Insertion of the Implant)

- Symptoms at incision site (such as pain, redness, swelling, numbness, rash, and tingling) occurred in about 6 out of 100 patients (about 6%).
- Vocal cord paresis (impaired motion of the vocal cord) occurred in about 5 out of 100 patients (about 5%). It was typically experienced as mild to moderate hoarseness, but it also included difficulty breathing or difficulty swallowing in two cases. Some patients elected to have additional treatment with speech therapy or injections of bulk fillers to the vocal cords.
- Hoarseness occurred in about 3 out of 100 patients (about 3%).
- Eye symptoms (eyelid swelling or drooping of upper eyelid) occurred in about 1 out of 100 patients (about 1%).
- Difficulty swallowing occurred in about 1 out of 100 patients (about 1%).

The following occurred in less than 1 out of 100 patients (less than 1%), all were non-serious:

- Headache or migraine
- Wound infection
- Complication with suture
- Cough
- Sore throat
- Difficulty breathing
- Diarrhea
- Rash
- Scar pain
- Inflammation and blood clot at intravenous (IV) site

Stimulation Therapy

Stimulation therapy was well-tolerated by patients. When patients reported symptoms considered related to stimulation, the symptoms either self-resolved over time or resolved with an adjustment to the strength of stimulation. The most common complaint was mild to moderate pain or discomfort related to stimulation, occurring in about 3 out of 100 patients (about 3%). Other symptoms, occurring in less than 1 out of 100 patients (less than 1%), are listed below.

- Toothache
- Retching
- Nausea
- Metallic taste
- Choking sensation
- Cough
- Sore throat
- Near fainting
- Poor quality sleep
- Spasm near device
- Jaw pain (TMJ)

Charger

One patient reported a rash after wearing the Charger.

Surgery (Removal of the Implant)

In one patient, the larynx (voice box) was accidentally injured. It was successfully repaired during the surgery and did not require hospitalization. Antibiotics and a drainage tube in the neck were required until the injury healed.

Appendix H – Cybersecurity

IT Configuration

A guide for more advanced IT configuration of the SetPoint System can be found on the SetPoint Medical Website at https://spm.care/it-guide. The IT guide contains the following information:

- Detailed technical descriptions of minimum networking requirements
- Diagrams for the home and healthcare use environment
- A list of all addresses and ports the SetPoint System uses for its connectivity
- Recommended networking encryption protocols
- Recommendations for IT-related cybersecurity hardening
- Details on data integrity and backup procedures
- Troubleshooting related to IT issues

Cybersecurity Software Updates

Known cybersecurity vulnerabilities found in the SetPoint System will be published as advisories on the SetPoint Medical website. Any advisories can be found at https://spm.care/cybersecurity-advisories. Software and firmware updates that remediate cybersecurity vulnerabilities can be obtained by bringing your SetPoint Medical devices to your healthcare professional.

Data Integrity, Backup, and Recovery

A fundamental tenet of the SetPoint System's data strategy is about what data is *not* collected or stored. Every effort is made to avoid collecting, transmitting, or storing data unless it is necessary to the functionality of the system. For example, none of the following pieces of information are ever stored on the Implant or Charger:

- Patient Names
- Usernames or Emails
- Location or Address Information
- Clinic Information
- Phone Numbers
- Date of Birth
- Race or Gender Information

Implant Integrity and Backups

The Implant ensures the integrity on all its non-volatile memory. In certain critical spaces, such as therapy parameters, redundant copies of data are kept. Where redundant data is available, and corruption or tampering is detected, an attempt will be made to restore a known-valid copy of the data. If corruption is detected on non-volatile program memory, the device will return to its bootloader – a state which is displayed on the Charger so that the user is made aware (see Appendix A - Charger LED Status).

Integrity checks are performed routinely, including every time an Implant is charged and every time an Implant powers up to perform autonomous stimulation. Therapy parameters are kept safe with redundant copies on the Implant. They are also preserved in the Cloud. Should all therapy parameters on the Implant be corrupted or erased, they will be automatically restored by Programmer fetching the data from the Cloud during the next clinic visit.

Charger Integrity and Backups

The Charger also ensures the integrity of all its non-volatile memory. In certain critical spaces, redundant copies of data are kept. Where redundant data is available, and corruption or tampering is detected, an attempt will be made to restore a known-valid copy of the data. If corruption is detected on non-volatile program memory, the device will return to its bootloader – a state which is displayed on the Charger so that the user is made aware (see the Appendix A - Charger LED Status). Integrity checks are performed routinely, including every time the Charger is placed on the Docking Station.

Decommissioning and Sanitizing the Charger's Data

The Charger stores the following Implant information in its non-volatile memory:

- A cached Implant Event Log, including the last-connected Implant's Model ID and Serial Number
- Key information for encryption with the Implant

This data is erased when connected to a new Implant. Only authorized and authenticated healthcare professionals are allowed to issue commands to read this data. The Charger leverages chip Readout Protection (RDP) modes to prevent any debuggers from accessing this data. Attempts to access this data with a debugger will result in erasing all memory on the device. No explicit steps are needed to sanitize or decommission a Charger.

Decommissioning and Sanitizing the Implant's Data

The Implant does not support deleting its data. Contact SetPoint Medical to request a return merchandise authorization (RMA) for the explanted Implant, if removed.

Responding to Cybersecurity Events

If you suspect a cybersecurity event has occurred, contact SetPoint Medical. SetPoint Medical has a team that monitors for cybersecurity events and will promptly respond to any cybersecurity threats. If you believe you have discovered a cybersecurity vulnerability in a SetPoint Medical product, please follow SetPoint Medical's Coordinated Vulnerability Disclosure process which can be found at https://spm.care/security.

Software Bill of Materials

An up-to-date Software Bill of Materials (SBOM) can be found on the SetPoint Medical Website at https://spm.care/sbom.

Cybersecurity End-of-Support

Cybersecurity support is offered through the expected operating duration of the devices (i.e., 5 years for the Charger and 10 years for the Implant). During this time, patients and healthcare professionals can expect cybersecurity updates to the Implant and Charger to address any vulnerabilities that may be discovered.